pugatchconsilium

ASCENDING TO THE PEAK OF BIOPHARMACEUTICAL INNOVATION

Biopharmaceutical Competitiveness & Investment (BCI) Survey, 4th Edition, 2017

This report was commissioned by the Pharmaceutical Research and Manufacturers of America (PhRMA). The views represented here are those of the authors only.

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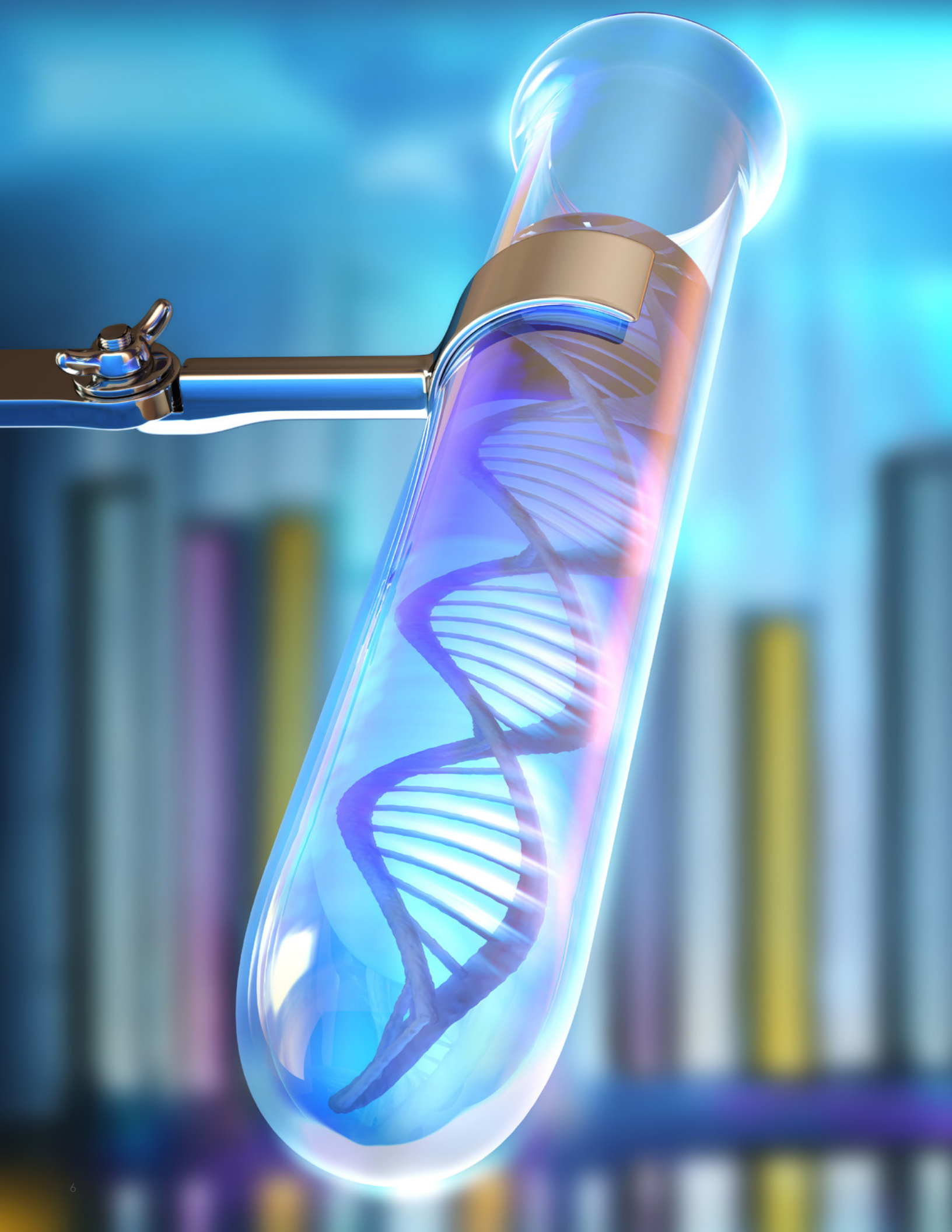
LIST OF ABBREVIATIONS

ANMAT	Administración Nacional de Medicamentos, Alimentos y Tecnología (Argentinian drug regulatory authority)
ANVISA	Agência Nacional de Vigilância Sanitária (Brazilian National Sanitary Surveillance Agency)
API	Active pharmaceutical ingredient
BRIC	Brazil, Russia, India and China
BRIC-MT	Brazil, Russia, India, China, Mexico and Turkey
CENABAST	Central Nacional de Abastecimiento (Chilean procurement agency)
CFDA	Chinese Food and Drug Administration
COFEPRIS	Comisión Federal para la Protección contra Riesgos Sanitarios (Mexico's drug regulatory authority)
CROs	Clinical research organizations
CTs	Clinical trials
DIPP	Department of Industrial Policy & Promotion (India)
FDI	Foreign direct investment
FTA	Free trade agreement
ICH	International Conference on Harmonisation
ICT	Information and communication technology
IND	Investigational new drug application
INN	International non-proprietary name
INVIMA	Instituto Nacional de Vigilancia de Medicamento (Colombia's drug regulatory authority)
IP	Intellectual property
M&A	Mergers and acquisitions
MHRA	Medicines and Healthcare Products Regulatory Agency (UK)
NDA	New drug application
NLEM	National List of Essential Medicines
OECD	Organisation for Economic Cooperation and Development
PAHO	Pan American Health Organization
PDP	Brazil's Productive Development Partnerships
PPH	Patent Prosecution Highway
PROSUR	Latin American regional cooperation system on IP
PTE	Patent term extension
RDP	Regulatory data protection
R&D	Research and development
ROSPATENT	Russian Patent Office
TIFA	Trade & Investment Framework Agreement
TUBITAK	Scientific and Technological Research Council of Turkey
UNCTAD	United Nations Conference on Trade and Development
USTR	US Trade Representative



EXECUTIVE SUMMARY

What does it take for economies today to reach the peak of biopharmaceutical innovation? Which economies are near the summit, and what policies have made them more likely to secure biopharmaceutical investment and have strengthened their ascent? Which economies are just starting the climb and what trajectory should they pursue in order to ensure they do not lose out on the investment needed to continue upward?

These questions are explored in the 2017 Biopharmaceutical Competitiveness & Investment Survey, a global executive opinion survey and index of economies' biomedical investment-attractiveness. The BCI Survey provides a comparatively more in-depth, holistic, and focused barometer of the biomedical environment in a given economy than, on the one hand, more general measures, and on the other hand, more policy-specific measures. In addition, by taking a "bottom-up" approach the BCI enables a unique and highly relevant snapshot of economies' biomedical competitiveness. Indeed, the respondents to the BCI Survey – country managers and their teams – often have a candid and accurate understanding of how different aspects of the local policy environment factor in when discussing whether to allocate further resources in the economy.

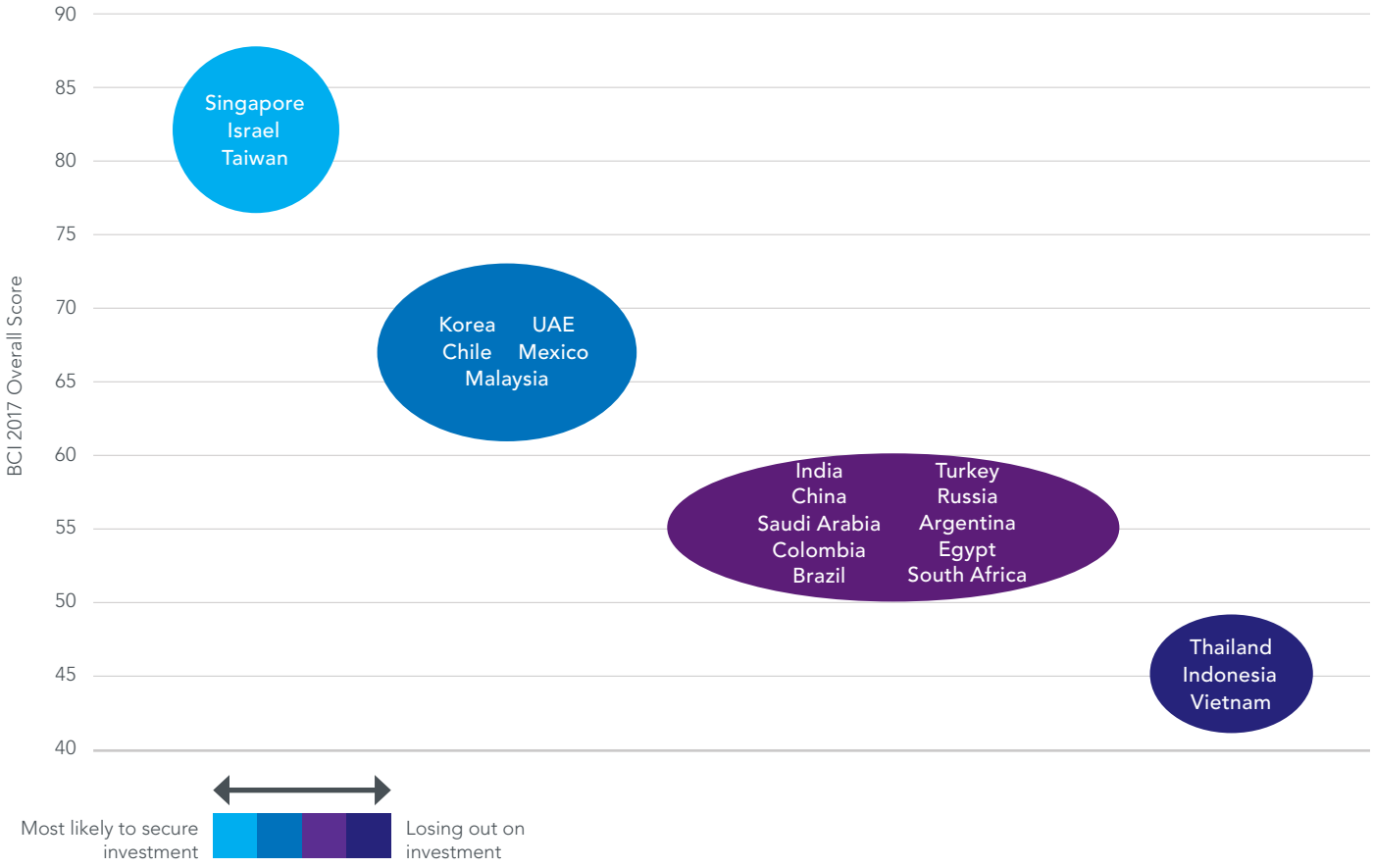
The fourth edition of the BCI Survey expands the economies covered to 31 markets and includes an even wider sample of developed and emerging economies, capturing many of the largest and most active biopharmaceutical markets worldwide. The below table lists the markets sampled in 2017.

Economies included in the fourth edition are divided into two groups, "mature" markets and "newcomer" markets. The division is based on sophistication of the health and biopharmaceutical system as well as extent of historical biopharmaceutical R&D and manufacturing capabilities. Each group is given a separate survey, which address overarching necessary policy conditions in 5 categories, from scientific and clinical capabilities to quality of the regulatory framework, market access conditions and the intellectual property (IP) environment, as well as recent pertinent policy issues in the given group of markets. For example, newcomer market-specific questions cover basic standards such as existence of and compliance with Good Manufacturing Practice and pharmacovigilance, while mature market-specific questions cover topics like availability of fast-track approval pathways and special pricing schemes for breakthrough treatments. Based on a statistical analysis of the responses each market is assigned a quantitative score (out of 100) and compared with other markets in the relevant group, newcomer or mature markets. As such, economies are gauged in relation to other markets with similar levels of development, allowing for an even more fine-tuned snapshot of each market's attractiveness for biopharmaceutical investment.

Newcomer markets				Mature markets	
Argentina	Brazil	Chile	China	Australia	Canada
Colombia	Egypt	India	Indonesia	Germany	Ireland
Israel	Malaysia	Mexico	Russia	Italy	Japan
Saudi Arabia	Singapore	South Africa	South Korea	New Zealand	Switzerland
Taiwan	Thailand	Turkey	UAE	UK	U.S.
Vietnam					

BCI 2017 Overall Results

Newcomer Markets



Key Finding #1: Policy conditions can make or break leaders in biopharmaceutical innovation

The most competitive markets in 2017 are those that grasp opportunities to leverage competitive advantages through supportive policies. Resting on large demand or dynamic economies is not enough. Many newcomer markets punch below their weight in competitiveness because of detrimental policies for biopharmaceutical innovators. Economies placing in the bottom two groups, like Russia, Indonesia, and Thailand, sabotage their significant innovation potential by relying on draconian and unpredictable pricing policies and IP regimes that critically harm innovators.

Even some markets considered in the past to be graduating to the "next level" – take Korea, Malaysia, Colombia, or Vietnam – are today falling behind due to measures undercutting global innovation. With the rise of its biotech sector often considered a success story among Asian markets, Korea's growing use of heavy-handed price and reimbursement controls represents a surprising divergence from an otherwise supportive policy environment and has colored executives' confidence in the market across the board. Colombia's efforts to become a regional clinical research hub are stymied by uncertainty over biosimilar approval, hostile pricing conditions, and discussions on compulsory licensing. Other economies' lack of forward movement is giving innovators pause. India, Mexico, and South Africa are examples of economies wavering or backtracking on commitments to strengthen their regulatory and IP systems, and experiencing drops or stagnating in their BCI scores.

At the same time, economies placing in the top, such as Singapore and Israel – and even some currently placing near the middle, such as China – are introducing measures that capitalize on and bolster existing strengths or latent potential in biopharmaceutical R&D. Though a top performer in all editions of the BCI Survey, in 2017 Singapore's renewed promotion of collaborative and international models of R&D, enhanced regulatory standards and compliance, and ongoing capacity building are recognized as huge draws for innovators. Israel, too, has made marked progress in establishing top quality life science research centers and a high level of connectedness with industry as well as augmenting funding for drug reimbursement in 2016-17 (though other market access challenges exist). With recent moves to speed up regulatory approval and shore up biopharmaceutical IP protection, on top of long-term efforts to create a world-class science base, China is an example of a market that is taking concrete steps that, if fully implemented, could move it up from the middle of the BCI rankings. The 2017 BCI results suggest that a practical commitment to getting a full range of the policy fundamentals right pays off in terms of biopharmaceutical competitiveness.

Key Finding #2: Enabling, rather than protecting, local innovators is the key to 21st century biopharmaceutical competitiveness

Supporting the growth of local biopharmaceutical industries lies in providing enabling conditions for all innovators, not preferring local companies at the expense of others. The acceleration of discriminatory conditions and prescriptive local investment in the past year has only made countries that in many ways should be rising biopharmaceutical stars, like Brazil, Indonesia, Russia, and Turkey less attractive in the eyes of innovators - key partners in advancing local sectors. Restricting loopholes in pricing rules, purchase guarantees, priority approval and technology transfer requirements to all but local companies, has meant these markets have fallen behind in their BCI ranking in 2017.

The future is in biopharmaceutical R&D and forcing investment in one area, such as manufacturing, while neglecting other enabling conditions is a missed opportunity for diving into the R&D space. Newcomer markets falling into the bottom two groups are often those with pockets of potential in R&D and clinical trials that are undermined by policies discriminating against innovators and inadequate focus on supportive policies.

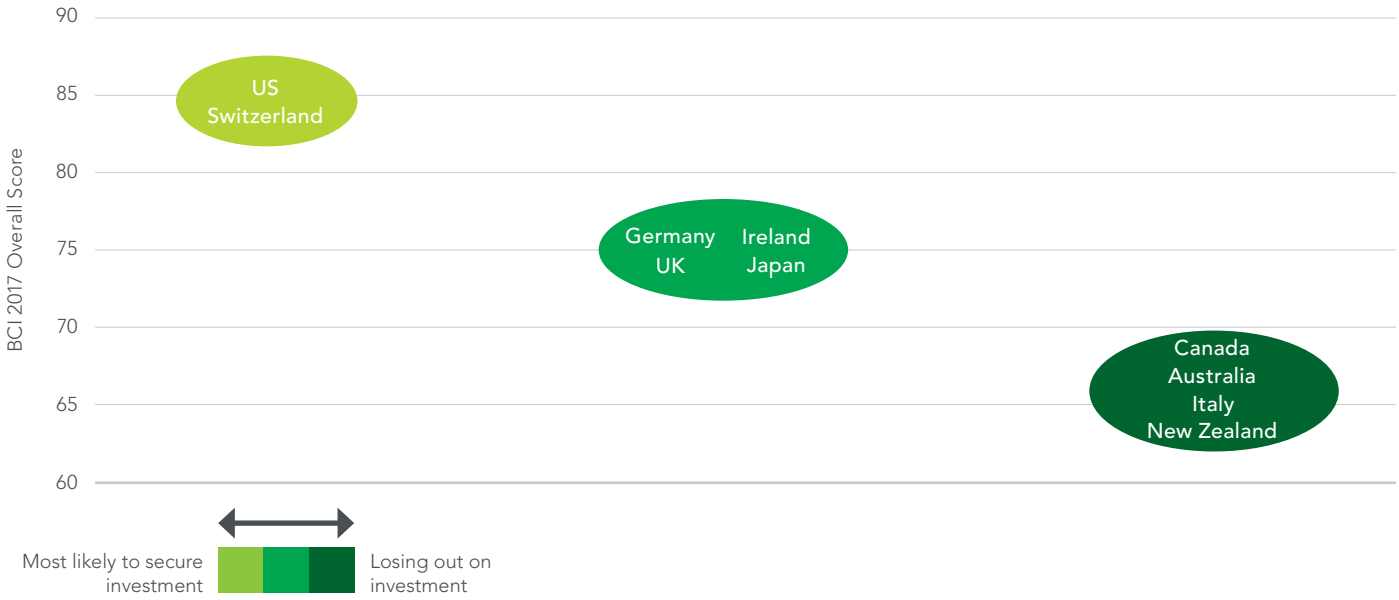
In fact, in a number of cases newcomer markets are making progress or perform considerably better in the areas of scientific capabilities and clinical research compared to the other BCI categories. Average scores in these two categories tend to be higher than the other categories (and by a substantial margin). Moreover, newcomer markets' performance in these two categories is improving each year. In 2017 the share of newcomer markets with a score of 60% or higher in scientific capabilities rose to nearly half (up from one third in 2016). Several other countries displayed jumps in their scientific capabilities scores though they remained low overall.

Many economies exhibit even greater strengths in the area of clinical research capacity and conditions. Economies' scores for the clinical research category were highest relative to other categories in nearly 70% of economies in 2017 (up from 60% in 2016). Within clinical research areas that stand out as being particularly strong and/or ones to leverage further (based on the questions with the highest average scores per country) include the level of capabilities and the willingness to be more active among local hospitals and the CRO industry, though executives often note that more coordination, dedicated funding, and international collaboration are needed to leverage these strengths.

What this means is that many newcomer markets possess real potential for developing and honing cutting edge R&D sectors. Employing harmful policies for innovators – foreign and domestic – in other aspects of the biopharmaceutical "ecosystem" is thus often out of sync with economies' efforts to promote domestic innovative activities, and undercuts these efforts. In contrast, newcomer markets scoring at the top of the BCI tend to have put in place a range of voluntary, market-based measures that spur investment from the laboratory to the marketplace.

BCI 2017 Overall Results

Mature Markets



Key Finding #1: Dismissing the value of innovation has a real impact on competitiveness

The continued rise of policies that undermine factors of innovation and de-prioritize it is having a detrimental effect on mature markets' ability to "stay in the game". Cost containment measures, discrimination against IP owners, and other policies that jettison support for innovation are top of mind for innovators making decisions about where to invest. This plays out in the 2017 BCI results. Several economies' competitiveness rating stalled or deteriorated in 2017, including the UK, Japan, Australia, and New Zealand's, on the back of increasing reliance on these types of measures.

The UK is a prime example of how effects of roll-back of reimbursement for innovative drugs and rigid pricing rules can ripple across other areas of the biopharmaceutical environment. The perceived expansion of strict cost containment measures without a concurrent increase in drug uptake has also affected the attractiveness of the UK as a clinical research hub (with executives reporting, for instance, reduced coverage of drugs required as comparators in trials). In turn, the UK fell from the top group to the middle group of mature markets in 2017. Japan's market access score also fell significantly, with instances of stiff price cuts levied against innovative drugs and discussion of more frequent re-pricing of medicines seen by executives as a concerning reversal of policies rewarding innovative drugs, such as the innovation-based Sakigake Strategy launched in 2014. The results are loud and clear – these markets are hampering their ability to secure or sustain cutting edge investment – and should be a red flag to other economies considering a similar approach (such as Canada, in its proposed amendments to the Patented Medicines Regulations).

Key Finding #2: A "nuts and bolts" approach is critical

The 2017 BCI results also suggest that what holds mature markets back is a lack of attention to detail in nurturing biopharmaceutical innovation. For instance, the most competitive markets are those that do not just grow spending on R&D but dedicate sufficient and consistent funding to research institutions and hospitals, promote

sophisticated scientific training, encourage collaborative, horizontal R&D, and continuously foster a strong policy environment.

New Zealand is an example of an economy that falls behind in the area of scientific capabilities, not just in its level of R&D spending overall (which is just over half of the OECD average at 1.3% of GDP[1]), but also in the way in which monies are spent. Executives surveyed cite a low level of funding for R&D-focused infrastructure and clinicians and barriers to collaboration between research institutions and industry (including what is considered to be an almost exclusive focus within the health system of constraining growth of health and medicines budgets).

When it comes to clinical research, "success stories" are countries that enhance a wide range of factors, from clinical capacity and resources to regulatory and ethics review efficiency, while still ensuring a predictable and patient-centered framework. Economies rated as relatively less competitive by innovators tend to display gaps in some specific areas of the biopharmaceutical policy environment (even if other areas are positive), compared to top-rated markets, where there is a more holistic approach to creating supportive conditions. For instance, Australia has developed a high quality science and clinical research base but executives display relatively low confidence in the clinical research environment overall, noting in particular a dearth of capabilities outside of state capitals and an inefficient ethics approval process undertaken at the institutional and state levels leading to significant delays.

1 AIMING FOR THE SKY: SUPPORTING AND MEASURING BIOPHARMACEUTICAL COMPETITIVENESS

As one of the leading innovative industries today, the research-based biopharmaceutical industry is an integral partner for supplying life-saving medicines, creating high-value jobs, and driving sustainable economic growth.

Securing investment in biopharmaceutical innovation is thus often a top priority in many economies' development strategies. But what steps can economies take to reach the peak of attractiveness for biopharmaceutical investment, and just as importantly, how can they gauge where they are on the "climb"? The 2017 edition of the Biopharmaceutical Competitiveness & Investment (BCI) Survey builds on previous editions to measure the relative attractiveness of economies to investment from biopharmaceutical research-based companies and provide governments and other key stakeholders with a snapshot of major markets' global competitiveness.

1.1 It's anyone's game: The realities of 21st century biopharmaceutical R&D

A vibrant biopharmaceutical sector today is far from a "one-size-fits-all" phenomenon, limited to certain economies or types of innovators. Rather, any country – large or small, developed or newly industrialized – can become a biomedical innovation hub. Indeed, according to the 2017 Global R&D Funding Forecast, the life sciences R&D industry is unique among other high-tech sectors in its global reach, with nearly a third of the top 50 life sciences organizations headquartered outside the US and Europe.[2] And biopharmaceutical R&D leadership is not only for large, established markets; in fact, some of the most well-known bioclusters outside of the US are located in small countries or those with up-and-coming life sciences sectors. Take for instance, Singapore's Biopolis, Denmark's Medicon Valley, Israel's Tel Aviv/Jerusalem/Haifa cluster, the Osong Bio Valley in Korea and China's Shanghai Zhangjiang Hi-Tech Park and Suzhou BioBay.[3]

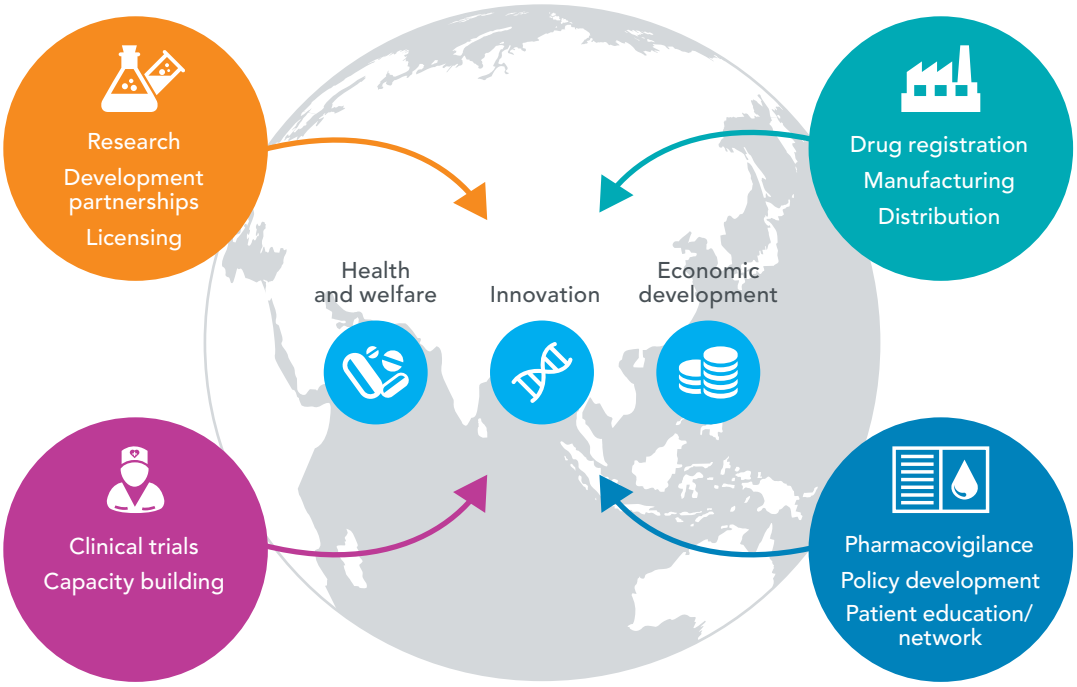
In addition, the "DNA" of biopharmaceutical innovators has become highly diverse and the lines between their respective portfolios blurred. No company is locked into a given segment or region and a great deal of cross-over occurs, from small biotech firms to the world largest biopharmaceutical multinationals, and even traditionally generic-focused companies.[4]

What this means is that, as Figure 1 suggests, any given economy can secure biopharmaceutical investment in all shapes and sizes. What is more, biomedical investment generates the numerous economic and welfare benefits of a knowledge-based field – from high-tech capacity building to homegrown innovative activities, from competitive domestic industries to the ability to meet demand created by growing and ageing populations and global health challenges.

1.2 The nuts and bolts of securing biopharmaceutical investment

How do governments and economies improve their competitiveness and secure a larger piece of global biopharmaceutical investment? Today it is well established in the empirical literature and in many countries' experience that economies seeking high-tech investment must actually put in place incentives and supporting conditions, rather than merely relying on market size, rate of growth, geographical location and even historical strengths.[5] Indeed, a number of economies today have put in place national innovation strategies, many targeting biopharmaceutical or biotech innovation, including specific reforms aimed at improving key factors of innovation.[6]

FIGURE 1 The range and benefits of biopharmaceutical investment



Source: Pugatch Consilium

The question facing developed and developing economies today is whether or not they will take a holistic or "ecosystem" approach to providing supportive conditions for biopharmaceutical investment. In other words, policies should promote activities spanning the entire lifecycle of research and development, from the discovery of new molecules to the launch and availability of cutting edge medicines in markets, and enable the cycle to begin again. These include support for developing scientific and clinical capabilities and infrastructure, an effective and efficient regulatory system and market access framework and robust intellectual property (IP) protections.

This also means that not only should supportive measures cover the full range of biopharmaceutical R&D they should also integrate the recognition that these components are not isolated factors, but rather are heavily intertwined. An improvement or deterioration in one area can have significant knock-on effects on other aspects of biopharmaceutical investment. For that reason, economies that tend to focus on promoting one segment or policy area at the expense of others are typically not successful in attracting biopharmaceutical R&D.

For example, a difficult market access environment in a given economy may have the effect not only of making an innovator less inclined or able to invest in the launch of products but also in a broader agenda, such as in clinical research or development partnerships, there. Similarly, the use of very specific requirements for investment, such as local content requirements, may result in minimal-level investments and dissuade wider investment in the economy's biopharmaceutical R&D system. On the other hand, a relatively open and supportive environment for manufacturing in one economy may also lead to, for instance, capacity building and joint ventures with domestic companies. Companies operating in economies that minimize uncertainty about regulatory timelines or IP protection are more likely to set up R&D centers or conduct clinical trials there.[7] Just as companies do, economies must also take an inclusive, "big picture" view

of investment conditions and understand what are the bottlenecks and lynchpins within the biopharmaceutical ecosystem.

Providing a supportive environment in all corners – and actively and continually working to maintain this support – directly translates into actual investment. One proxy of high-level and sustained biopharmaceutical investment is the intensity of clinical research. Looking at the rate of clinical trial activity in a sample of major markets (Figure 2), the majority of countries that display a relatively high rate of clinical research (100 trials or more registered to date in the NIH registry, Clinicaltrials.gov, per million population) are those that are rated more highly in global competitiveness rankings like the BCI Survey.

But how can economies assess where they stand in providing a strong biopharmaceutical ecosystem and in their associated level of attractiveness for investment from biopharmaceutical innovators?

1.3 The context, rationale and scope of the BCI Survey

Previous editions of the BCI have discussed various tools for mapping biopharmaceutical policy conditions, including those that measure investment competitiveness more generally, those that focus on the biotech and biopharmaceutical sectors specifically and those that measure targeted policy areas.[8] These measures rely on a combination of hard data from existing metrics and on surveys. Taken together all of these tools provide a picture of economies' competitiveness for investment and innovation worldwide. One piece largely missing from this toolbox is a measure specifically looking at the biopharmaceutical sector that draws on the on-the-ground perspective from innovators about the likelihood of investing in a given economy and what factors tend to drive or deter investment there.

FIGURE 2 Biopharmaceutical policy environment (BCI 2017 score) and rate of investment (clinical trial activity)

Source: Pugatch Consilium; Clinicaltrials.gov (2017)

*NB: Clinical trial activity measured by number of clinical trials to date registered in Clinicaltrials.gov as of May 2017; BCI scores for newcomer and mature markets based on separate surveys and scored separately

In its fourth edition in 2017, the BCI Survey, a global executive opinion survey and index of economies' biopharmaceutical investment-attractiveness, aims to fill this gap.

The BCI relies on statistically established survey modeling tools, including those used in the Global Competitiveness Index and Doing Business report, but refocuses them on the biopharmaceutical field. In total, the BCI provides a comparatively more in-depth, holistic and focused barometer of the biopharmaceutical environment in a given economy than, on the one hand, more general measures, and on the other hand, more policy-specific measures. In addition, by taking a "bottom-up" approach, though still with results in a quantitative format, the BCI enables a unique and highly relevant snapshot of economies' biopharmaceutical competitiveness. Indeed, the respondents to the BCI Survey – country managers and their teams – often have a candid and accurate understanding of how different aspects of the local policy environment factor in when discussing whether to allocate further resources in the economy.

The BCI Survey examines the entire ecosystem in which biopharmaceutical innovation takes place by examining the following major areas:

- ability to leverage scientific capabilities and infrastructure;
- state of the clinical environment, from test tube to patient;
- soundness and effectiveness of the biopharmaceutical regulatory framework and quality of biopharmaceutical manufacturing;
- market access conditions and healthcare financing; and
- strength of intellectual property protections pertaining to biopharmaceuticals.

Using statistical analysis respondents' answers are translated into a quantitative score, which is used to benchmark economies' performance and overall attractiveness for investment (a full description of the BCI methodology is provided in the following section).

In doing so, the BCI captures a wealth of data and observations concerning major areas of the biopharmaceutical environment, providing new insights on policy strengths and challenges in the sampled markets. The insights generated by the BCI may be of value in several different ways and for different stakeholders. The BCI provides a common, numeric and global measure of biopharmaceutical competitiveness that may be used by governments, biopharmaceutical companies and other organizations to understand and compare economies' performance on a like-for-like basis. As a quantitative measure of investment attractiveness the BCI may also be used to analyze the relationship between various policy inputs and investment outputs. In addition, on an individual economy basis the BCI scores shed light on the particular areas for improvement in a given economy in terms of the total biopharmaceutical ecosystem as well as specific areas/categories within the ecosystem. As such, the BCI is an evidence-based platform for supporting efforts to strengthen the biopharmaceutical policy environment at the national, regional and global levels.

2 THE METHODOLOGY AND PROCESS OF THE BCI 2017

The BCI is a global executive opinion survey and index of economies' biopharmaceutical investment-attractiveness. The BCI is composed of two parts: 1) a survey completed by multinational biopharmaceutical executives; and 2) statistical analysis and translation of the responses into a quantitative score. This section will describe the components of the survey and the process of obtaining responses and define the methodology used to calculate the scores.

2.1 The composition of the BCI Survey

The fourth edition of the BCI expands the economies covered to 31 markets. The economies represented in this edition are (most of the) members of the G20 plus 13 additional markets selected on the basis of their contribution to world GDP and trade and relative size of the biopharmaceutical market. As such the 31 markets included in the BCI in 2017 capture many of the largest and active biopharmaceutical markets worldwide. Table 1 lists the markets sampled in 2017.

Since 2016, to capture the wide range of markets included in this edition the BCI Survey has been split into two separate surveys, one targeting "mature" markets and the other, "newcomer" markets. This division is based on sophistication of the health and biopharmaceutical system as well as extent of historical biopharmaceutical R&D and manufacturing capabilities. The two surveys have been collected, scored, and analyzed separately.

Condensed into 25 questions each, around 60% of the questions in both surveys are the same or similar, addressing overarching necessary policy conditions in five categories:

1. Scientific Capabilities & Infrastructure

The biopharmaceutical innovation system is driven by several science and technology "push factors", including investment in biopharmaceutical R&D, a steady source of cutting edge advances in the life sciences and a sustained supply of physical and human resources available and utilized for biopharmaceutical innovation.[9] Specific elements that are often identified are: a sufficient quantity of highly-skilled biomedical professionals and researchers; scientific infrastructure; the presence of research clusters; technology transfer frameworks and financial support for R&D, including both public and private investment.[10] For instance, federal funding aimed at fundamental biomedical research by universities and public research institutions has been identified as a key element of biomedical discovery in the US, and a basis for drug development.[11]

TABLE 1 Economies covered in the BCI 2017 by market group

Newcomer markets				Mature markets	
Argentina	Brazil	Chile	China	Australia	Canada
Colombia	Egypt	India	Indonesia	Germany	Ireland
Israel	Malaysia	Mexico	Russia	Italy	Japan
Saudi Arabia	Singapore	South Africa	South Korea	New Zealand	Switzerland
Taiwan	Thailand	Turkey	UAE	UK	U.S.
Vietnam					

In this light, the questions in this category assess the quality of personnel, technologies and facilities in biopharmaceutical research forums in the economy; the extent of collaboration between public and private research partners; and the ability to leverage these to translate discoveries into products.

2. Clinical Research Conditions & Framework

Conducting clinical trials is part of an extensive process for determining which compounds out of hundreds under investigation may be further developed and eventually brought to market, and in what manner. Clinical research enables companies and drug regulators to ensure that new drugs will be safe and effective for use. It also often uncovers novel applications of medicines and medical devices or facilitates tailoring drugs to different populations. Furthermore, it provides a wide number of social and economic benefits to patients, health systems and national economies, including advance access to innovative drugs, opportunities for local participation in cutting edge research and clinical standards and improvements to infrastructure.[12]

From an investment perspective, biomedical companies seek clinical trial sites in which they can conduct trials both in a way that would bring them value, as well as provide the most effective means of collecting data. Therefore, companies consider a wide range of factors when deciding to conduct clinical trials in a given economy. These factors include: the characteristics of the population related to the specific product to be tested; the availability and willingness of the population to participate throughout the duration of the trial; the infrastructure of local hospitals and research centers; the ability of physicians and supporting medical staff to carry out clinical trials and work with international organizations; the ease of the regulatory system, including approval of clinical trials; and the costs of performing the trials in the economy.[13]

In this light, the questions in this category assess the ability of research institutions in the economy to conduct clinical research in a high quality and efficient manner.

3. The Regulatory System – Drug Approval, Quality Assurance and Pharmacovigilance

The regulatory environment in a given economy plays an important role in shaping incentives for investment and establishing adequate levels of quality and safety for biomedical products. Inadequate approval standards may promote the presence of substandard drugs in the market, which could affect demand for high quality drugs and discourage investment in new products.[14] Conversely, a strong regulatory environment creates the conditions for the production and sale of high quality products and technologies.[15] While complying with these standards may impose substantial costs on manufacturers it also gives patients and health care providers confidence that new biomedical products are safe and effective.

High regulatory standards tend to refer to those which assess the quality, safety and efficacy of products to a high level, according to the International Conference on Harmonisation's (ICH) standards and require a system for monitoring products once they are in the market (known as pharmacovigilance).[16] These standards vary depending on the type of product, whether it be a completely new drug application (NDA), a generic or a biosimilar, with generic approval needing to include bioequivalence testing and biosimilar approval a higher standard that goes beyond bioequivalence testing.[17]

In this light, the questions in this category assess the ability of the regulatory system in the economy to ensure that only high quality, safe biopharmaceutical products enter the market, yet do so in a timely manner.

4. Market Access & Financing

Most health care systems today have in place either direct or indirect mechanisms for regulating the pricing and reimbursement of medicines. Prices are often determined by governments through complicated formulas of reference pricing that compare the cost of medicines within a therapeutic area or across a number of countries. Many countries have also adopted systems of health technology assessment to inform pricing and reimbursement decisions.

In other more diversified health systems such as in the US, the price and cost of medicines is to a greater extent influenced by market-based factors and negotiation. However, payers – be they public bodies or private health insurers – still set formularies and reimbursement guidelines.

The continued rise of chronic disease and associated health care costs in mature and emerging markets has put more pressure on health authorities and payers to limit future increases in health spending through different pricing, reimbursement and procurement policies. The manner and extent to which these policies are put in place can have a profound impact on the incentives for biomedical investment.[18] Academic research and modeling suggests that restrictive pricing and reimbursement policies limit and delay investment in a market, reducing new biomedical product launches.[19]

In this light, the questions in this category assess the ability of new biopharmaceutical products to access the market via the pricing, reimbursement and procurement system in the economy in an efficient manner and at an appropriate price.

5. Effective IP Protections

Over the last decade a number of empirical studies have been published on the positive and cumulative effect of IP protection on investment generally. For instance, one OECD study found that a 1% change in the strength of a national IP environment (based on a statistical index) is associated with a 2.8% increase in FDI in-flows.[20]

In relation to the life sciences, IP rights play at least two major roles: 1) provide a guarantee of temporary market exclusivity that facilitates a return on investment and further re-investment in R&D; and 2) act as a platform for transferring technologies among R&D entities. Hence, a strong legal basis for IP protection as well as its enforcement in a given market assures biomedical companies and other investors that their IP assets will be protected from infringement as they develop, test and launch products in that market.

In particular, patents and other forms of exclusivity for biomedical products, such as regulatory data protection and special exclusivity incentives for the protection and production of orphan drugs, provide research-based companies with an incentive to invest vast sums in R&D and the discovery of new biomedical products and technologies. The research process for biomedical products is unique in its time, cost and high rate of failure. The market exclusivity period provided by IP rights gives firms the protection and incentive needed to recoup R&D investments made. Evidence suggests that many drugs and therapies would not have been discovered had it not been for the incentive and protection provided by these IP rights.[21]

Equally important for biomedical products is the on-the-ground enforcement of IP protections. Key concerns for biomedical investors are the extent to which the production and availability of infringing products, including counterfeits, are limited and deterred.

In this light, the questions in this category assess the ability to fully realize required terms of intellectual property protections for biopharmaceutical products. On this basis Figure 3 outlines the key elements of each of the five categories of the BCI Survey – the major policy conditions necessary for biopharmaceutical innovation globally.

Each category is designed to evaluate respondents' views of an economy's performance in a different area of the ecosystem in which the biopharmaceutical innovation life cycle takes place. These questions seek to provide a comprehensive, relevant and accurate picture of an economy's performance at different segments of the biopharmaceutical "pipeline", and hence its attractiveness for investment.

In addition, each survey covers policy issues that are pertinent to the given market group, newcomer or mature. For example, newcomer market-specific questions cover basic standards such as existence of and compliance with Good Manufacturing Practices and pharmacovigilance

FIGURE 3 The policy ecosystem supporting biopharmaceutical innovation based on the BCI Survey

Source: Pugatch Consilium, based on the 2017 Biopharmaceutical Competitiveness & Investment (BCI) Survey (Pugatch Consilium, forthcoming)

and presence of delays between market approval in a given market and approval by the FDA or EMA. Mature market-specific questions cover topics like the availability of fast-track approval pathways and special pricing and reimbursement schemes for breakthrough treatments and new research areas.

The full text of both surveys may be viewed in the Appendix to this report.

As in 2016 for each question, respondents rate an economy's performance in relation to a certain benchmark. Figure 4 gives examples of the benchmarks used in three survey questions, 1 common to each survey; 1 from the newcomer market survey and 1 from the mature market survey. In Question 10 (Question 9 in the mature market survey), an adequate independent capacity for review and approval of new biopharmaceutical products in line with international standards provides the benchmark. The benchmark used in Question 11 in the mature market survey is the availability of designated fast-track pathways with demonstrated success in enabling the timely introduction of priority innovative products. For Question 24 in the newcomer market survey, the benchmark is the existence of a regulatory mechanism that ensures timely and effective patent enforcement.

FIGURE 4 Sample questions from the BCI Survey

Question 10 in newcomer market survey (Question 9 in mature market survey)
How would you describe the capacity of the health regulator in your country to review the data submitted to it for the approval of new biopharmaceutical products?

Very low (low capacity for independent review)	Basic (most reviews based on prior approval in other countries; lacks significant capacity for independent review)	Good (review based on prior approval in other countries as well as on independent review)	Excellent (full capacity to conduct independent review)
☐	☐	☐	☐

Question 11 in mature market survey
To what extent do designated fast-track pathways for priority innovative biopharmaceutical products exist in your country?

None (such pathways do not exist at the moment)	Basic (framework for a fast-track pathway(s) exist but are not actually operational or effective)	Satisfactory (designated fast-track pathways are in place and are being used)	Excellent (fast-track pathways are fully operational and produce concrete results in terms of the ability to introduce priority products to the market)
☐	☐	☐	☐

Question 24 in newcomer market survey
In your view, how effective are civil and criminal remedies for infringement of intellectual property rights and battling counterfeit medicines in your country?

Highly ineffective (framework for litigation and penalties does not exist)	Fairly ineffective (framework exists but is generally not implemented or enforced)	Fairly effective (framework is generally implemented and enforced but with key exceptions)	Very effective (including compensation, injunctions, seizures and penalties; ability to challenge validity of a patent)
☐	☐	☐	☐

Source: BCI Survey (2016)

In order to capture specific nuances of economy performance, respondents select from a scale of four answers for each question. This scale ranges from the lowest possible performance to the highest possible performance (i.e., the benchmark), but the exact scale varies for each question. This design gives respondents a framework for gauging their views, but in a way that minimizes constraining their answers as much as possible.

2.2 Execution of the 2017 BCI Survey

The 2017 BCI Survey was distributed primarily to general managers of multinational research-based biopharmaceutical companies operating in the 31 sampled economies – in other words, experts in the field and on-the-ground practitioners with deep knowledge of the local biopharmaceutical investment environment in a given economy The 2017 BCI Survey was conducted during the second quarter of 2017, though some economies' response period occurred before or after this.

When asked about the utility and accuracy of the BCI, the overwhelming majority of respondents have found the BCI to be a useful tool for assessing the biopharmaceutical ecosystem. In the view of over 90% of respondents, most, if not all, of the questions covered relevant elements of an economy's attractiveness for biopharmaceutical investment.

2.3 Calculation and classification of scores

As in 2016, based on a statistical analysis of the responses, each market is assigned a quantitative score (out of 100). Each market is only compared with other markets in the relevant group, newcomer or mature markets. As such, economies are gauged in relation to other markets with similar levels of development, allowing for an even more fine-tuned snapshot of each market's attractiveness for biopharmaceutical investment.

For both surveys, to score the responses each question accounts for a total of 4 points. The four answer options for each question correspond to scores of 1, 2, 3 and 4 – ranging, in order, from the options reflecting the poorest to the highest performance. Based on the analysis of responses to all 25 questions, each economy receives a score for each category as well as an overall score, out of a maximum of 100.

Based on category and overall scores, economies are classified into levels of competitiveness for biopharmaceutical investment and innovation globally relative to the other sampled markets in each group. Newcomer markets are divided into four groups, with the upper and lower ends based on the distribution of the scores (which follows a typical bell curve pattern in which the scores are concentrated in a certain score range, in this case roughly between 40 and 90), ranging from those most likely to secure investment to those losing out on investment. Mature markets are divided into three groups with a similar progression (within a score range of about 60 to 90 out of 100).

3 OVERALL FINDINGS OF THE 2017 BCI SURVEY

3.1 Newcomer markets

Overall results

Figure 5 presents the overall results for the 21 newcomer markets covered in the 2017 BCI Survey.

Key Finding #1: Policy conditions can make or break leaders in biopharmaceutical innovation

The most competitive markets in 2017 are those that grasp opportunities to leverage competitive advantages through supportive policies. Resting on large demand or dynamic economies is not enough. Figure 5 suggests that many newcomer markets punch below their weight in competitiveness because of detrimental policies for biopharmaceutical innovators. Economies placing in the bottom two groups, like Russia, Indonesia, and Thailand, sabotage their significant innovation potential by relying on draconian and unpredictable pricing policies and IP regimes that critically harm innovators.

As Table 2 indicates, even some markets considered in the past to be graduating to the "next level" – take Korea, Malaysia, Colombia, or Vietnam – are today falling behind due to measures undercutting global innovation. With the rise of its biotech sector often considered a success story among Asian markets, Korea's growing use of heavy-handed price and

FIGURE 5 BCI 2017 Overall scores: Newcomer markets

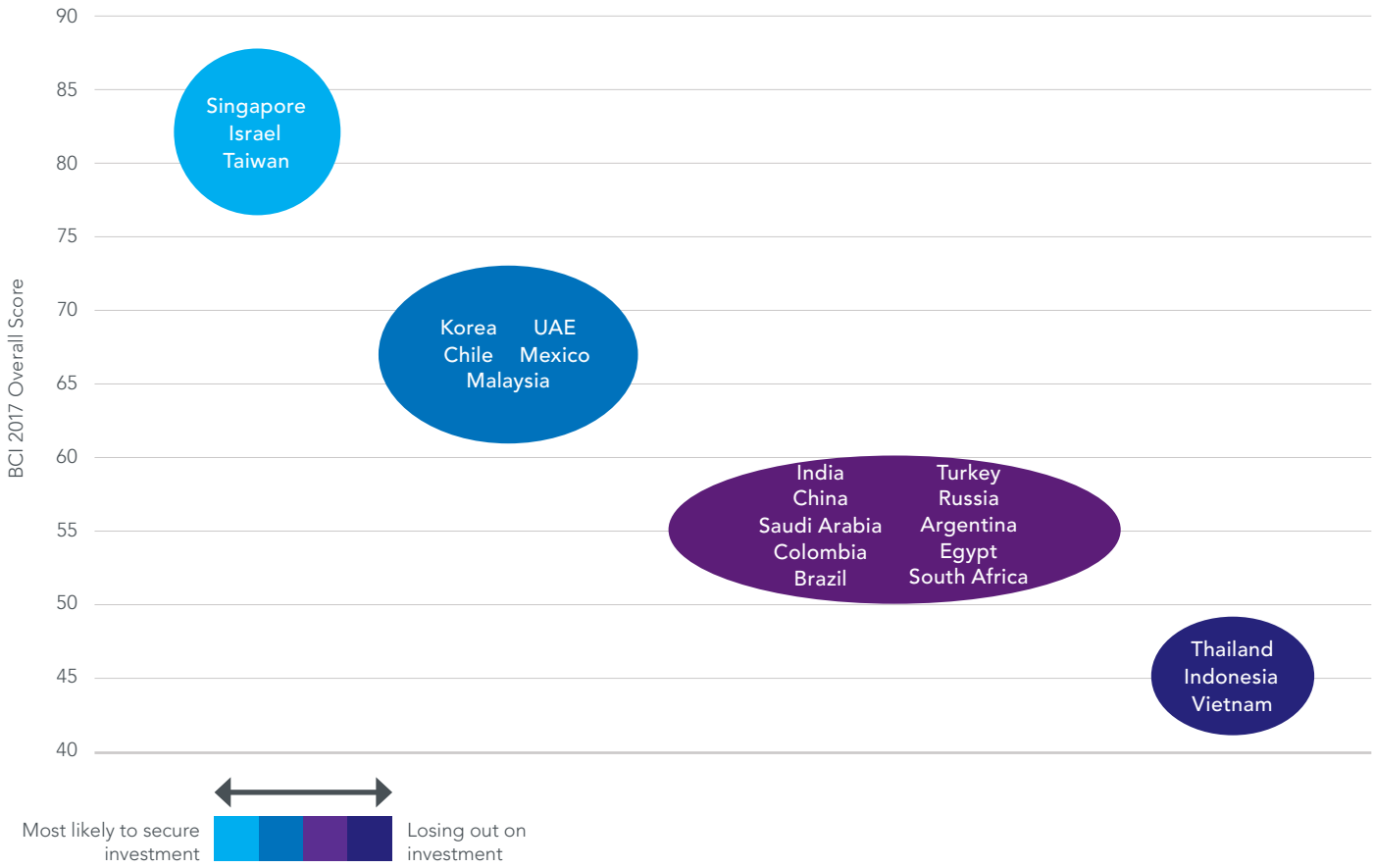


TABLE 2 Newcomer Markets: Year on Year Change, 2017 vs. 2016

Newcomer Markets	Score Change (>2%) vs. 2016	Newcomer Markets	Score Change (>2%) vs. 2016	Newcomer Markets	Score Change (>2%) vs. 2016
Singapore	↑	Malaysia	2017 only	Russia	↔
Israel	↑	India	↔	Argentina	↔
Taiwan	↔	China	↑	Egypt	↔
Korea	↓	Saudi Arabia	↓	South Africa	↓
Chile	2017 only	Colombia	↔	Thailand	↔
UAE	↔	Brazil	↔	Indonesia	↓
Mexico	↓	Turkey	↓	Vietnam	2017 only

● Score rose ● Score remained the same (<2% change in score) ● Score fell

reimbursement controls represents a surprising divergence from an otherwise supportive policy environment and has colored executives' confidence in the market across the board. Colombia's efforts to become a regional clinical research hub are stymied by uncertainty over biosimilar approval, hostile pricing conditions, and discussions on compulsory licensing. Other economies' lack of forward movement is giving innovators pause. India, Mexico, and South Africa are examples of countries wavering or backtracking on commitments to strengthen their regulatory and IP systems, and experiencing drops or stagnating in their BCI scores.

At the same time, economies placing in the top group in Figure 5, such as Singapore and Israel – and even some currently placing near the middle, such as China – are introducing measures that capitalize on and bolster existing strengths or latent potential in biopharmaceutical R&D.

Though a top performer in all editions of the BCI Survey, in 2017 Singapore's renewed promotion of collaborative and international models of R&D, enhanced regulatory standards and compliance, and ongoing capacity building are recognized as huge draws for innovators. Israel, too, has made marked progress in establishing top quality life science research centers and a high level of connectedness with industry as well as augmenting funding for drug reimbursement in 2017 (though other market access challenges exist). With recent moves to speed up regulatory approval and shore up biopharmaceutical IP protection, on top of long-term efforts to create a world-class science base, China is an example of a market that is taking concrete steps that, if fully implemented, could move it up from the middle of the BCI rankings. The 2017 BCI results suggest that a practical commitment to getting a full range of the policy fundamentals right pays off in terms of biopharmaceutical competitiveness.

Policy focus: Market access and IP challenges drive deterioration in BCI scores among newcomer markets in 2017

For the countries with falling or already weak biopharmaceutical competitiveness in the 2017 BCI results, which policy-related factors are behind these trends? Comparing performance of newcomer markets over the past two editions of the BCI, the areas of market access and IP protection have displayed the steepest drops in scores. While the average scores for other BCI categories have, on balance, remained the same, between 2016 and 2017 average scores for these two categories fell by 3%, with drops of up to 20% for some economies.

Market access and IP gaps also stand out as driving forces when looking at which categories hamper countries' ranking the most relative to other categories of the BCI – in other words, in which category countries score the lowest. As Figure 6 indicates, in 2016 around a third of newcomer markets scored the lowest in the Market Access & Financing category. In 2017, this figure rose to over 50% of newcomer markets, suggesting that damaging policies around pricing, reimbursement, and procurement are spreading globally.

Although the policy challenges vary by country, the lowest average responses in the market access category are seen in questions examining the scope and effect of price controls and the level of transparency within the pricing and reimbursement system. Figure 6 also suggests that the extent to which IP challenges are weighing down economies' competitiveness is rising too, in tandem with the visibly growing use of barriers to biopharmaceutical IP rights, including by

FIGURE 6 Areas of weakness among newcomer markets (in terms of share of countries scoring the lowest in a given category)

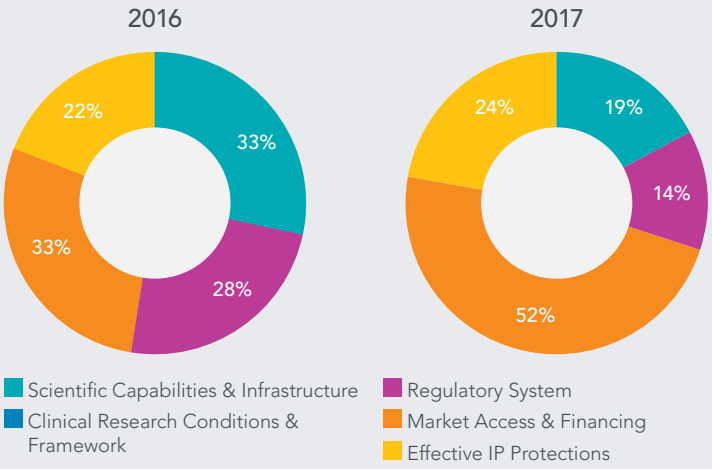
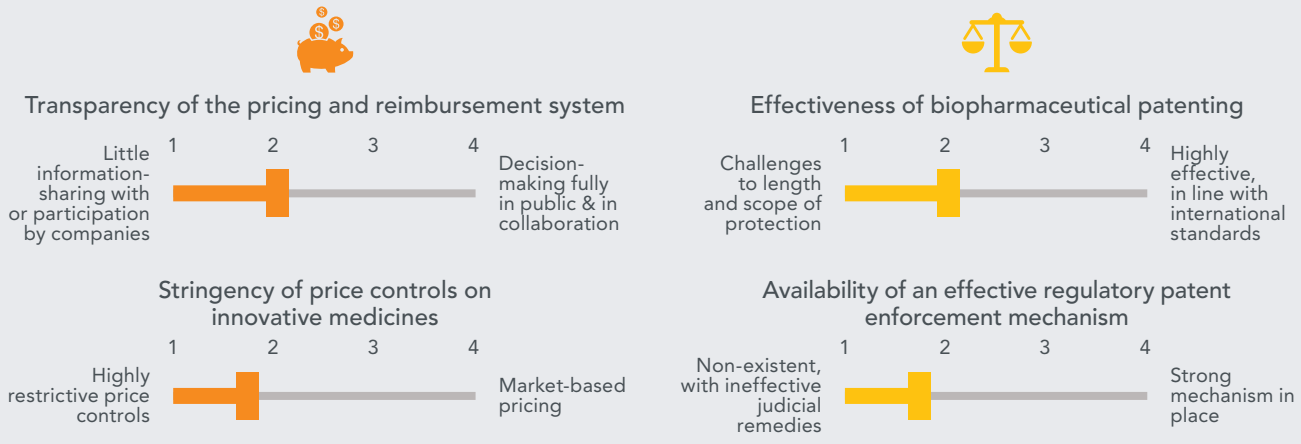


FIGURE 7 The most pressing challenges within Market Access and IP Protection (in terms of areas with the lowest average score among newcomer markets)



* Slider indicates average score among all newcomer markets

industrial, health, and drug regulators. Gaps in patent enforcement and the lack of an effective regulatory mechanism for ensuring timely enforcement of biopharmaceutical patents are among areas with the lowest scores in the IP category.

A number of economies slid from poor to even worse conditions in these two categories. In the area of market access, Korea's score dropped over 20%, with executives sensitive to a widening number of biopharmaceutical price controls and lack of predictability along with new price preferences for local products. In the IP Protections category Indonesia dropped nearly 5 percentage points from one of the lowest scores to the lowest among BCI markets, on the back of a further narrowing of patenting standards that single out biopharmaceuticals and use of IP exceptions to secure lower prices as part of its new patent law.

Economies added in 2017 also displayed particular challenges in these areas. For instance, Vietnam scored under a quarter of the total possible score in both the Market Access and IP Protections categories, with stringent and discriminatory price controls on imported products; uncertainty over the future of tenders for innovative products; narrow patenting criteria; and weak IP enforcement noted by executives as stifling competitiveness.

Others with previously fairly supportive environments stumbled significantly in 2017, notably Saudi Arabia, whose score in the IP Protections category plummeted by nearly one third. Executives raised strong concerns around what is seen as a cumulative lack of respect of Saudi IP laws by local biopharmaceutical regulatory authorities.

Key Finding #2: Enabling, rather than protecting, local innovators is the key to 21st century biopharmaceutical competitiveness

Supporting the growth of local biopharmaceutical industries lies in providing enabling conditions for all innovators, not preferencing local companies at the expense of others. The acceleration of discriminatory conditions and prescriptive local investment in the past year has only made countries that in many ways should be rising biopharmaceutical stars, like Brazil, Indonesia, Russia, and Turkey less attractive in the eyes of innovators – key partners in advancing local sectors. Restricting loopholes in pricing rules, purchase guarantees, priority approval, and technology transfer requirements to local companies only, among other policies, these markets have fallen behind in their BCI ranking in 2017.

The future is in biopharmaceutical R&D and forcing investment in one area, such as manufacturing, while neglecting other enabling conditions is a missed opportunity for diving into the R&D space. Newcomer markets falling into the bottom two

groups are often those with pockets of potential in R&D and clinical trials that are undermined by policies discriminating against innovators and inadequate focus on supportive policies.

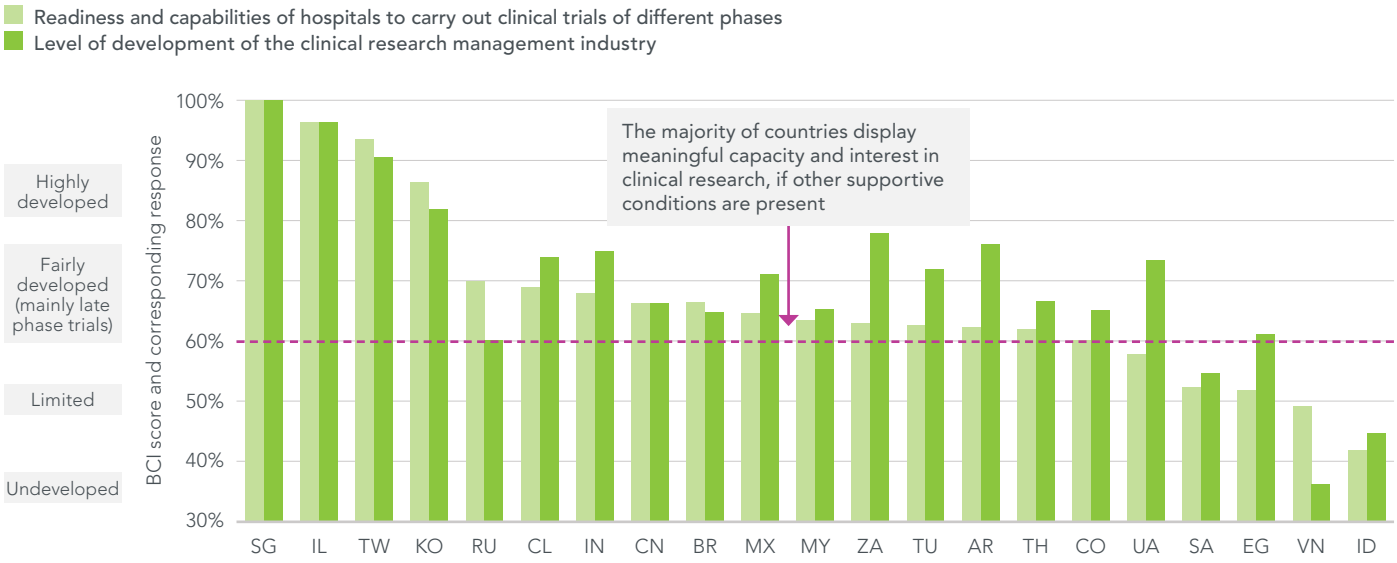
In fact, in a number of cases newcomer markets are making progress or perform considerably better in the Scientific Capabilities & Infrastructure and Clinical Research Conditions categories compared to the other BCI categories. Average scores in these two categories tend to be higher than the other categories (and by a substantial margin of about 15% for clinical research conditions). Moreover, newcomer markets' performance in these two categories is improving each year. In 2017 the share of newcomer markets with a score of 60% or higher in scientific capabilities rose to nearly half of economies (up from one third in 2016). Several other countries displayed jumps in their scientific capabilities scores though they remained low overall, including Brazil, Russia, Turkey, and India.

Many economies exhibit even greater strengths in the area of clinical research capacity and conditions. Economies' scores for the clinical research category were highest relative to other categories in nearly 70% of economies in 2017 (up from 60% in 2016). As Figure 8 indicates, within clinical research areas that stand out as being particularly strong and/or ones to leverage further (based on the questions with the highest average scores per country) are the level of capabilities and willingness to be more active among local hospitals and the CRO industry, though executives often note that more coordination, funding, and international collaboration are needed to leverage these strengths.

What this means is that many newcomer markets possess real potential for developing and honing cutting edge R&D sectors. Employing harmful policies for innovators – foreign and domestic – in other aspects of the biopharmaceutical ecosystem is thus often out of sync with other efforts to promote domestic innovative activities, and undercuts these efforts. In contrast, newcomer markets scoring at the top of the BCI tend to have put in place a range of voluntary, market-based measures that spur investment from the laboratory to the marketplace.

FIGURE 8 Areas of strength among newcomer markets: Focus on clinical research conditions

On average, newcomer markets score the highest in the Clinical Research Conditions & Framework category, and the areas within this category with the highest average scores are:

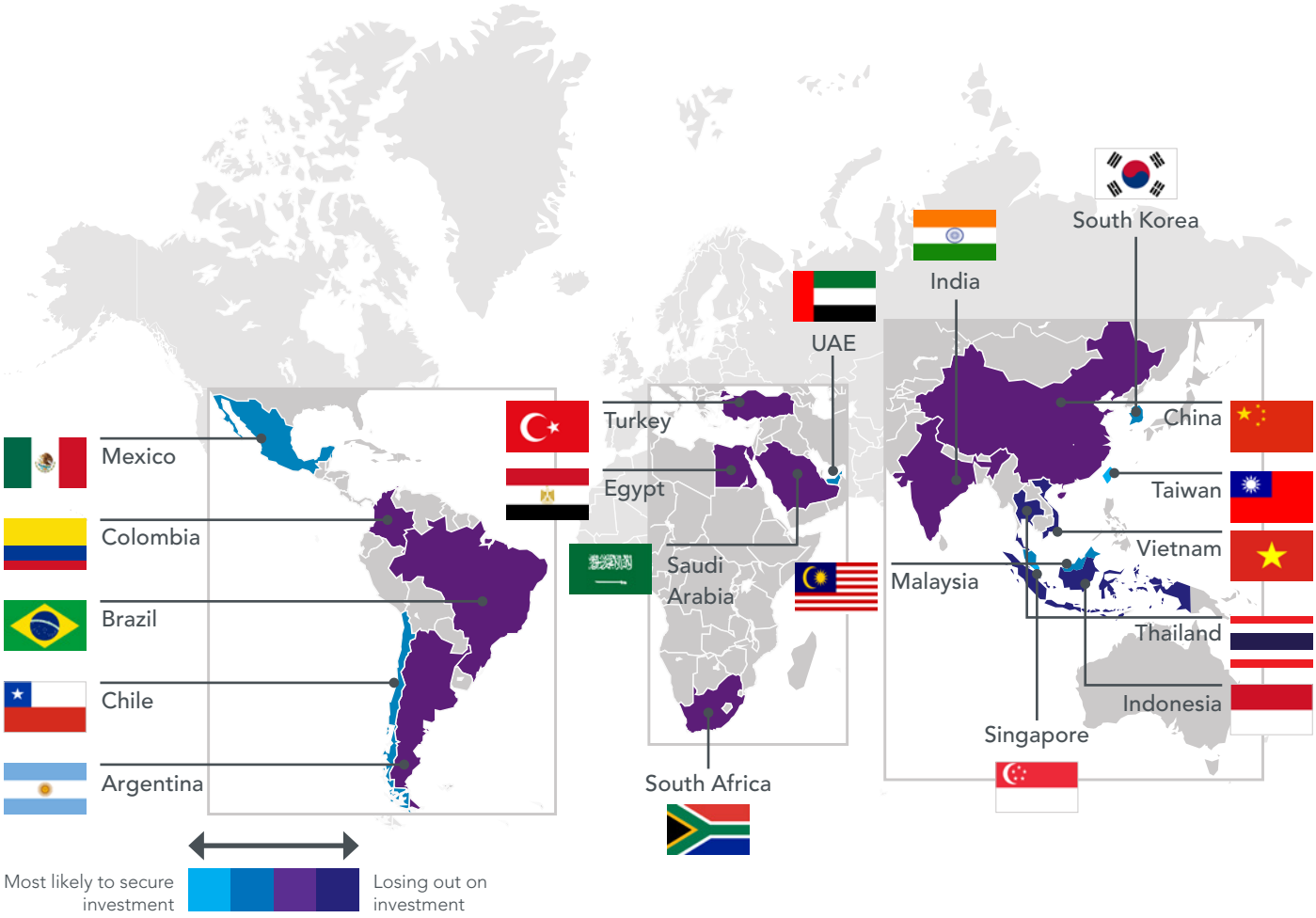


Lessons for ascending to the peak of biopharmaceutical innovation: Regional guideposts?

Who is implementing these lessons and seeing results? Are there countries that are trending toward the top of the peak of biopharmaceutical innovation and rated by executives as relatively more attractive for biopharmaceutical investment? Though every economy faces its own challenges and unique environment, in the major regions covered in the BCI certain economies stand out as relatively stronger performers and "guideposts" for other countries in the region – at least in certain areas.

As mentioned, two out of three in the top group of newcomer markets are two of the "Asian Tigers", Singapore and Taiwan. For a number of years both have provided targeted support to innovation through investment in R&D, high quality science education and infrastructure, and special platforms for technology transfer and industry-academic collaboration. They have also striven to implement international best practices in their regulatory and IP systems. For example, building on a strong basis in the ICT sector, Taiwan has over the past decade put in place a number of initiatives to boost its biopharmaceutical R&D and clinical research capabilities and today these are rated by executives as some of the strongest among newcomer markets. Taiwan has also worked to align its regulatory system with international standards and create a pro-technology IP framework, though some gaps still remain to be closed for it to compete with mature markets (including resolving approval delays, introducing greater predictability and holistic approaches in market access, and

FIGURE 9 BCI results among select newcomer markets by region



pushing through reforms to RDP and the patent linkage mechanism).

In the Middle East & Africa region, the UAE and Saudi Arabia have carved a new path in terms of the regulatory framework with high standard drug regulatory authorities and implementing new fast-track procedures for approval of innovative medicines. In the UAE this has already led to a number of innovative and groundbreaking products being registered within months of US or EU approval and made available to patients in the Emirates. In 2017, Egypt followed suit and announced the introduction of a similar pathway. Having said that, in other areas these countries are backtracking; both UAE and Saudi Arabia experienced marked drops in their scores for the IP Protections category in 2017 on the back of ongoing concerns over enforcement of pharmaceutical patents and RDP.

In the Latin America region, Chile and Mexico stand out as being relatively competitive compared to their major counterpart economies in the region, including Argentina and Brazil. Similar to UAE and Saudi Arabia, one factor enhancing Mexico's competitiveness includes the introduction of a more integrated market authorization procedure with shorter timelines. Mexico has also implemented improvements to its national IP environment including availability of patents for biopharmaceuticals and RDP for new chemical entities (though, again, executives cite need for further strengthening of patent enforcement and RDP, especially for biologics). For its part, Chile represents a success story for the region when it comes to development of biopharmaceutical R&D capabilities. Though it spends a relatively low percentage of GDP on R&D, executives view very positively the manner in which this funding has been allocated and the advances achieved in terms of R&D capacity and sophistication in Chile. Executives credit the Chilean Economic Development Agency CORFO for designing programs attracting entrepreneurs, targeted R&D investment, and global partnerships in clinical research, though some work remains in terms of implementing standards and knowledge in major clinical settings. Chile also risks undermining these advances and its leadership in R&D with regulatory barriers to carrying out clinical trials imposed under the recent Ricarte Soto Law and challenges around biopharmaceutical patents and compulsory licensing. For its part, in Argentina executives display some optimism toward future policy measures of the Macri administration but have not, as of yet, identified a concrete improvement in the biopharmaceutical policy environment specifically.

3.2 Mature markets

Overall results

Figure 10 presents the overall results for the 10 mature markets covered in the 2017 BCI Survey.

Key Finding #1: Dismissing the value of innovation has a real impact on competitiveness

The continued rise of policies that undermine factors of innovation and de-prioritize it is having a detrimental effect on mature markets' ability to "stay in the game". Cost containment measures, discrimination against IP owners, and other policies that jettison support for innovation are top of mind for innovators making decisions about where to invest. This plays out in the 2017 BCI results. As Figure 10 and Table 3 indicate, several economies' competitiveness rating stalled or deteriorated in 2017, including the UK, Japan, Australia, and New Zealand's, on the back of increasing reliance on these types of measures.

The UK is a prime example of how effects of roll-back of reimbursement for innovative drugs and rigid pricing rules can ripple across other areas of the biopharmaceutical environment. The perceived expansion of strict cost containment measures without a concurrent increase in drug uptake has also affected the attractiveness of the UK as a clinical research hub (with executives reporting, for instance, reduced coverage of drugs required as comparators in trials). Indeed, the UK's score dropped 8-10% in 2017 compared to 2016 in the Clinical Research Conditions & Framework, Regulatory System and Market Access & Financing categories and overall the UK fell from the top group to the middle group of mature markets in 2017. In addition, executives expressed concerns in relation to Brexit and uncertainty surrounding the cost implications for companies of a drug registration process separate from the European pathway.

FIGURE 10 BCI 2017 Overall scores: Mature markets

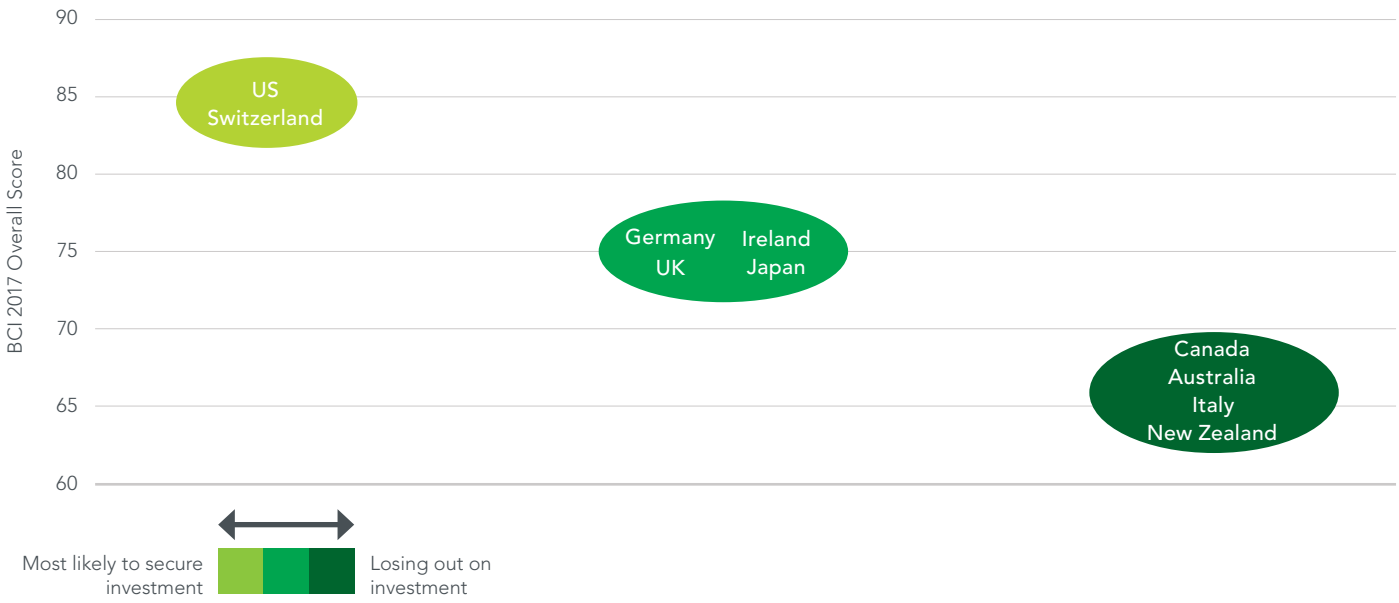


TABLE 3 Mature Markets: Year on year change, 2017 vs. 2016

Mature Markets	Score Change (>2%) vs. 2016	Mature Markets	Score Change (>2%) vs. 2016
US	↔	Japan	↓
Switzerland	↔	Canada	↓
Germany	↔	Australia	↔
UK	↓	Italy	↔
Ireland	↔	New Zealand	2017 only

● Score rose ● Score remained the same (<2% change in score) ● Score fell

Japan's market access score also fell significantly, with instances of stiff price cuts levied against innovative drugs and discussion of more frequent re-pricing of medicines seen by executives as a worrying reversal of policies rewarding brand new drugs, such as the innovation-based Sakigake Strategy launched in 2014.

The results are loud and clear – these markets are hampering their ability to secure or sustain cutting edge investment – and should be a red flag to other economies considering a similar approach.

Even for economies that do not necessarily experience a significant drop in their BCI score the area of market access emerges as the weakest link in their biopharmaceutical environments, even more in 2017 compared to previous years. As seen in Figure 11, the Market Access & Financing category is by far the space in which mature markets are rated lowest by executives, with the average score dropping an additional 7% between 2016 and 2017. A deeper dive into the questions in this category in Figure 12 sheds light on factors that particularly drive this deterioration, including the severity of cost containment measures and more fundamentally whether channels exist to recognize significant advances in therapeutic effectiveness.

Figure 12 also suggests that relative to other categories mature markets are beginning to struggle somewhat to compete effectively in clinical research, in part due to rising costs and an often complex and delayed review system. In contrast, where newcomer markets exhibit major gaps in IP protection, mature markets tend to have in place world-class IP regimes, with many (though not all) economies providing a high level of support through key biopharmaceutical IP rights.

Key Finding #2: A "nuts and bolts" approach is critical

The 2017 BCI results also suggest that what holds mature markets back is a lack of attention to detail to nurturing biopharmaceutical innovation. For instance, the most competitive markets are those that do not just grow spending on R&D but dedicate sufficient and consistent funding to research institutions and hospitals, promote sophisticated scientific training, encourage collaborative, horizontal R&D, and continuously foster a strong policy environment.

New Zealand is an example of an economy that falls behind in the area of scientific capabilities, not just in its level of R&D spending overall (which is just over half of the OECD average at 1.3% of GDP[22]), but also in the way in which monies are spent. Executives surveyed cite a low level of funding for R&D-focused infrastructure and clinicians and barriers to collaboration between research institutions and industry (including what is considered to be an almost exclusive focus within the health system of constraining growth of health and medicines budgets).

When it comes to clinical research, "success stories" are countries that enhance a wide range of factors, from clinical capacity and resources to regulatory and ethics review efficiency, while still ensuring a predictable and patient-centered framework. Economies rated as relatively less competitive by innovators tend to display gaps in some specific areas of the biopharmaceutical policy environment (even if other areas are positive), compared to top-rated markets, where there is a more holistic approach to creating supportive conditions. For instance, Australia has developed a high quality science and clinical research base but executives display relatively low confidence in the clinical research environment overall, noting in particular a dearth of capabilities outside of state capitals and an inefficient ethics approval process undertaken at the institutional and state levels and leading to significant delays.

Policy focus: Market access and regulatory delays are the weakest links for mature markets

FIGURE 11 Areas of weakness among mature markets (based on average BCI score per category, 2016-2017)

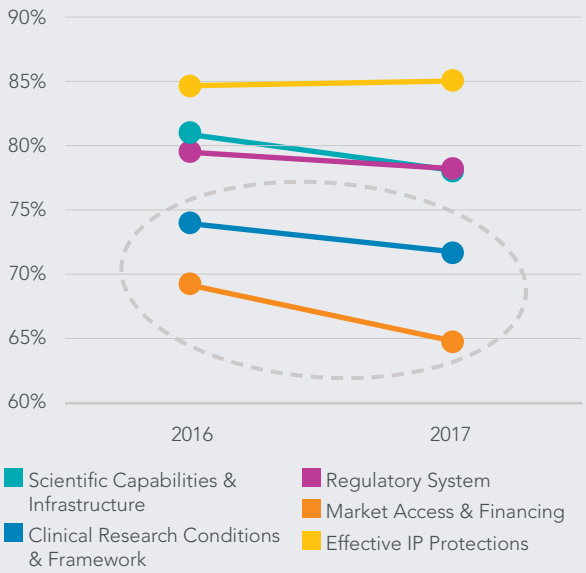
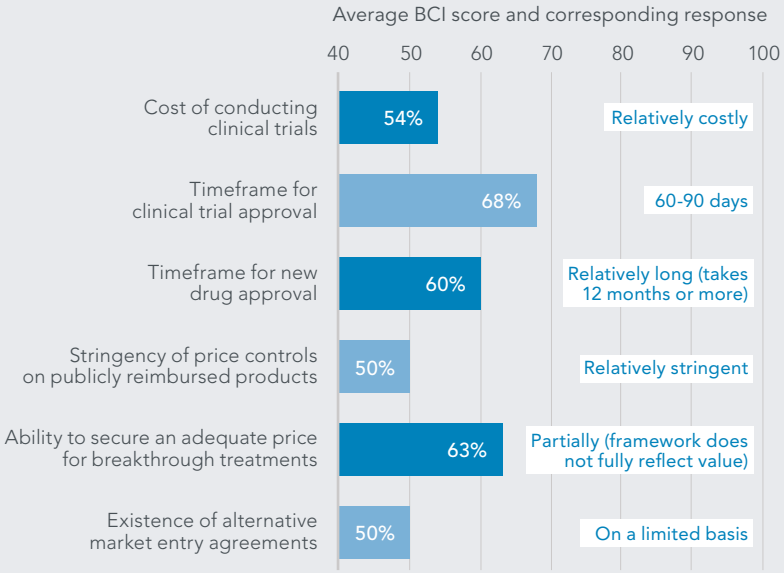


FIGURE 12 Areas with the lowest average score among mature markets



4 ECONOMY-SPECIFIC FINDINGS AND PROFILES

Introduction

This section presents a summary and analysis of each individual economy's overall and category scores. The section is divided into newcomer markets and mature markets, with profiles in each sub-section presenting the results of the respective survey.

Each profile first displays the overall BCI score in relation to the top scoring economy in each sampled group – Singapore among newcomer markets and the US among mature markets – as well as the average score in the relevant region or peer group. In their profiles, Singapore and the U.S. are compared to the average score of the top 5 economies in their respective market group. Where possible, the overall score is also presented in comparison to a market's score in the previous two editions of the BCI Survey (markets added in 2017 are presented with their respective investment attractiveness classification).

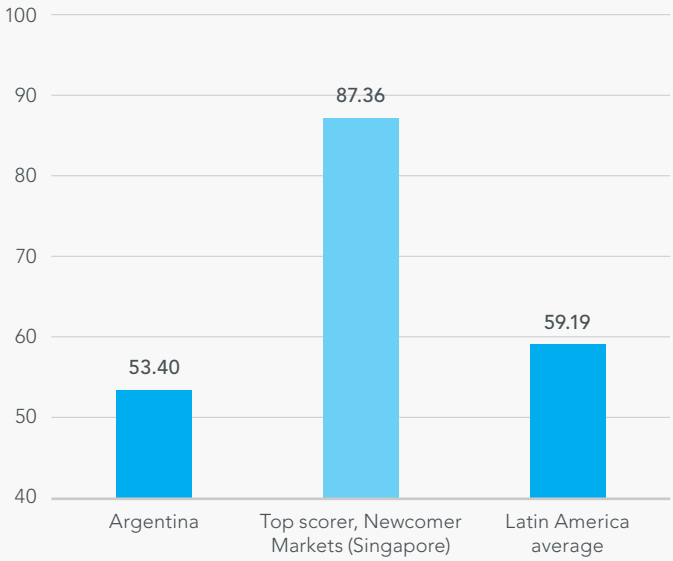
The profiles also provide a comparative analysis of the economy's score and performance by category (in terms of share of the total possible score), both in relation to the top scoring economy in the group as well as how economies' scores are changing over time. In this respect, year-on-year trends in an economy's category scores are examined in terms of which scores rose, fell or stayed the same and which categories represent the driving factors behind a given economy's performance (based on the top and bottom scoring categories relative to the other categories). For economies added in 2017 instead of year-on-year trends, this section presents economies' category scores in light of whether they support or undermine biopharmaceutical competitiveness.

Finally, drawing on BCI responses and comments, a more in-depth analysis and explanation of the economy's BCI scores is provided. This section includes the key strengths, weaknesses, and trends identified by executives.

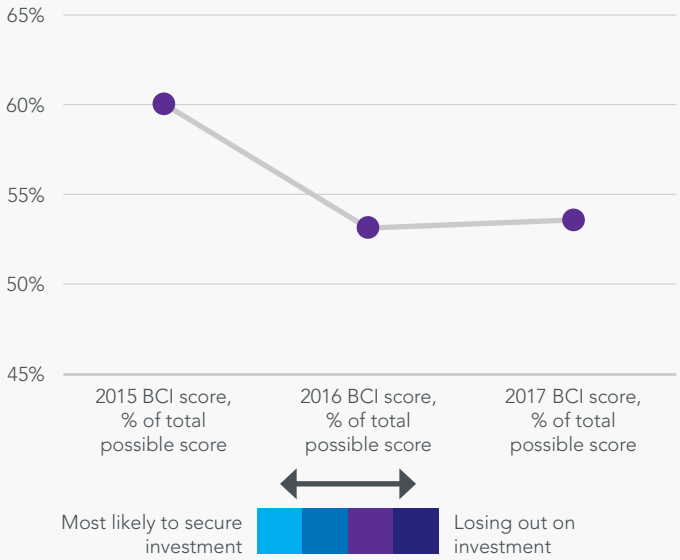
ARGENTINA

BCI Survey 2017 – Overall Scores

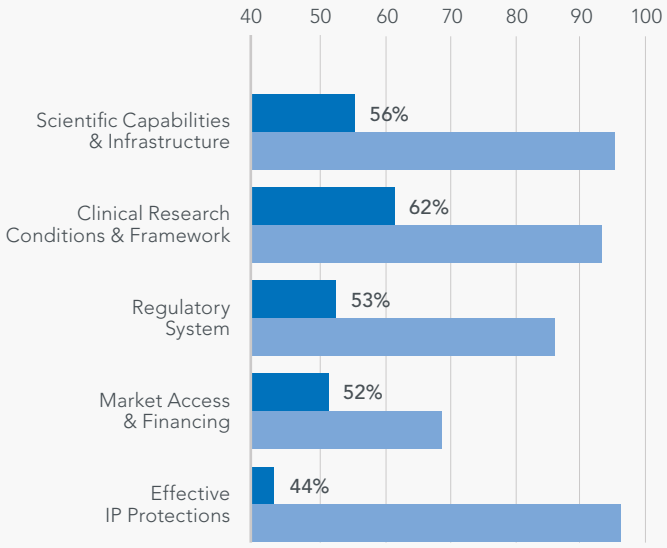
Comparison to Newcomer Markets



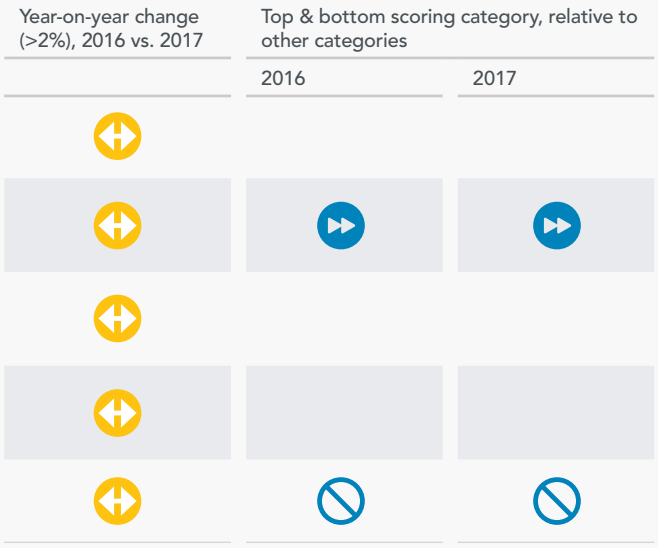
2015-2017



BCI Survey 2017 – Category Scores



Argentina, % of total possible score
Top scorer, Newcomer Markets (Singapore), % of total possible score



Score rose · Score remained the same (<2% change in score) · Score fell
Top scoring category (LOW indicates a top scoring category <60% or where significant challenges remain) · Bottom scoring category

BCI Results In Depth: What helps and what hinders Argentina's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✘ Though academic and research entities are viewed as sophisticated and executives welcome recent efforts to strengthen innovation (such as establishment of the Innovation and Creativity Forum under the TIFA with the US), focus is mainly on other sectors and capabilities remain basic in relation to biopharmaceutical R&D.
- ✘ Executives regard opportunities for collaborative R&D and technology transfer in biopharmaceuticals as not properly leveraged.

Clinical Research Conditions & Framework

- ✔ Private clinical research capabilities (especially among CROs), including generally high compliance with global clinical standards (GCP), are seen as a relative strength, though not used to their full potential.
- ✘ Long clinical trial approval delays, red tape and gaps in technical capacity at ANMAT remain an impediment, though ANMAT recently committed to shorten timelines.

The Regulatory System

- ✘ Executives expressed concern that scrutiny of *similares* remains limited and capabilities and standards for review of biosimilars inadequate and out of sync with WHO guidelines.
- ✔ Capacity for review of new biopharmaceutical products is considered more developed and up to international standards.

Market Access & Financing

- ✘ Executives report that pricing and reimbursement models continue to be focused on the lowest price, and formularies do not factor in pharmacoeconomic data and quality.
- ✘ Stricter requirements applied to foreign companies and low rate of inclusion of new treatments in public reimbursement and procurement impact negatively on business plans.

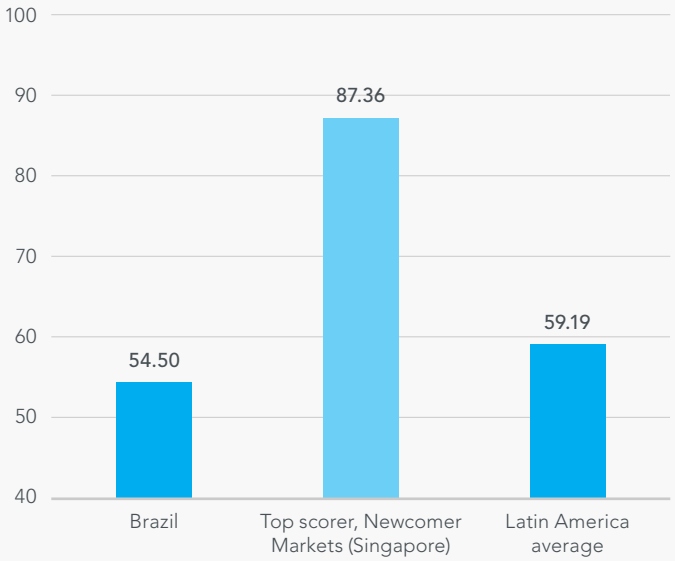
Effective Intellectual Property Protections

- ✘ Summary rejections of biopharmaceutical patents and lack of effective patent enforcement and RDP continue to weigh against greater investment.
- ✔ Consensus exists that efforts to modernize the patent office and speed up pendencies (such as through hiring of additional examiners and creation of Patent Prosecution Highways with the US and ProSur) are positive steps.

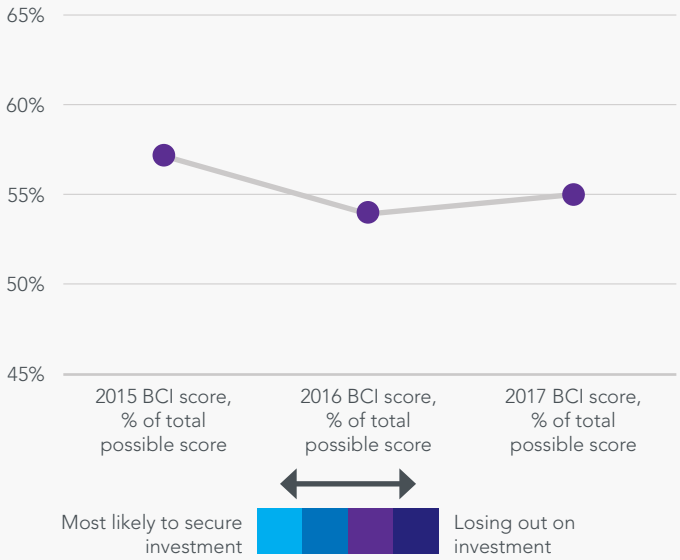
BRAZIL

BCI Survey 2017 – Overall Scores

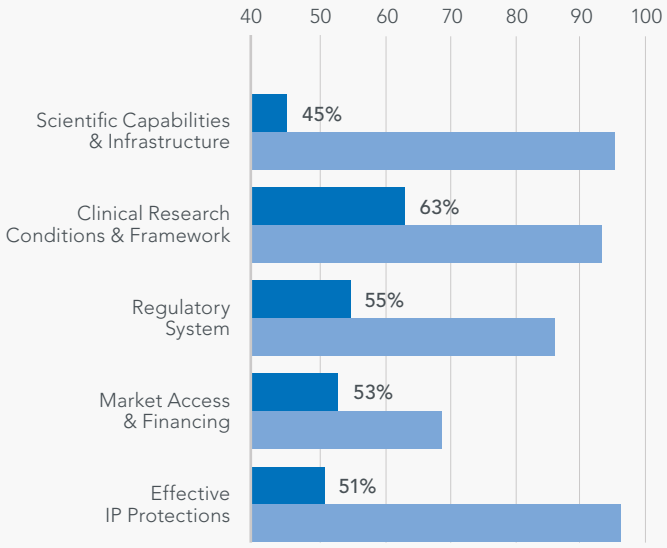
Comparison to Newcomer Markets



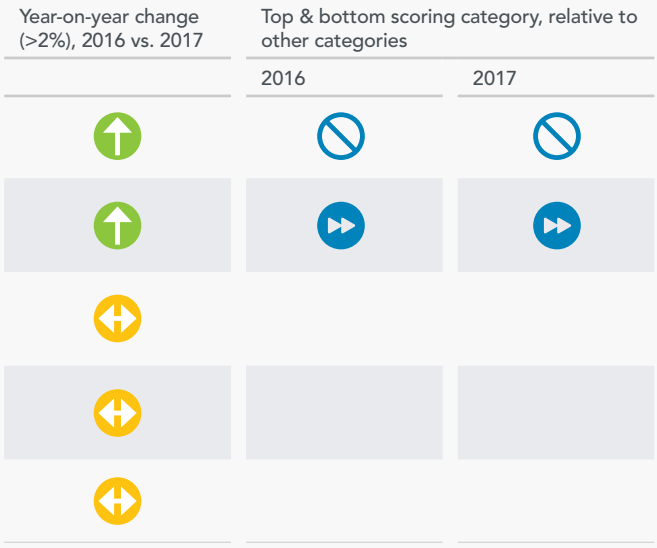
2015-2017



BCI Survey 2017 – Category Scores



Brazil, % of total possible score
Top scorer, Newcomer Markets (Singapore), % of total possible score



Score rose
Score remained the same (<2% change in score)
Score fell
Top scoring category (LOW indicates a top scoring category <60% or where significant challenges remain)
Bottom scoring category

BCI Results In Depth: What helps and what hinders Brazil's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✘ Though they view the level of funding for R&D more positively in 2017, executives see no comprehensive, long-term national policy or cohesive set of strategies to help modernize Brazil's scientific infrastructure and boost the volume of R&D professionals.
- ✘ Respondents note that the Brazilian PDP model has not led to a measurable increase in biopharmaceutical R&D capabilities, with PDPs often requiring extension due to inability to produce the medicine locally.

Clinical Research Conditions & Framework

- ✘ Executives cite excessive approval times for clinical trials – particularly for biologics – but welcome Law 200, which if implemented is expected to improve the accreditation of ethics committees and allow for fast track approval of clinical trial protocols.
- ✔ Clinical research capabilities among hospitals and CROs are viewed as fairly developed, with some room for improvement.

The Regulatory System

- ✘ Executives view drug approval as remaining excessively slow, unpredictable, and lacking in transparency.
- ✔ While respondents are encouraged by ANVISA's practice to routinely require more stringent evaluation of biosimilars (including clinical testing), some concerns exist about the possibility of using a less strict pathway.

Market Access & Financing

- ✘ Executives report a poor environment: very few innovative medicines are included in the national formulary, reimbursement is increasingly convoluted and cost-based, and ANVISA gives preferential treatment to local companies in the public procurement system.
- ✘ High taxes on imports are also mentioned as an additional barrier to accessing the market.

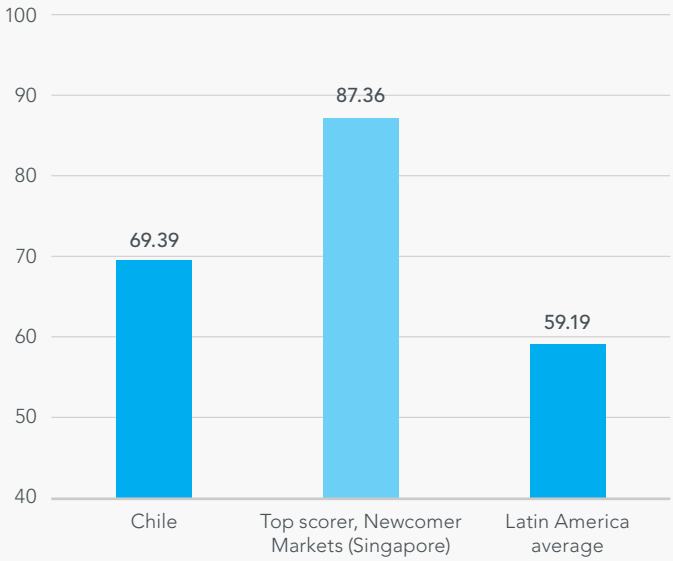
Effective Intellectual Property Protections

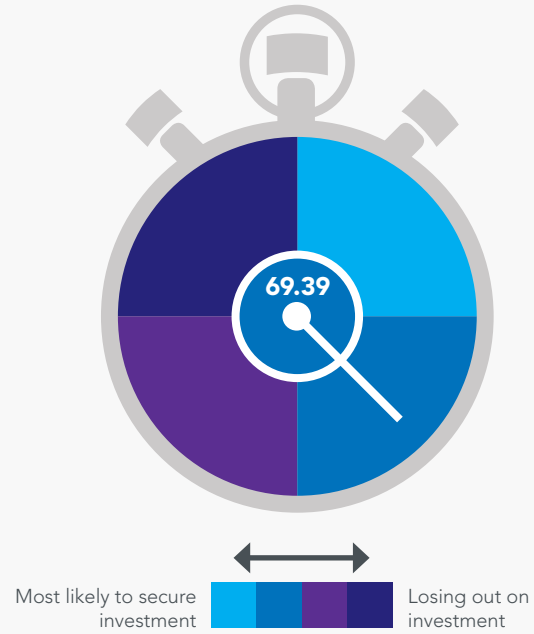
- ✘ Executives note that creation of the Patent Prosecution Highways with the U.S. and ProSur does not necessarily include pharmaceutical patent applications and may therefore not address the 10 year+ backlog.
- ✘ Concern remains regarding the policy of dual examination by ANVISA and INPI (including that it may have been reinforced through the two agencies' recent agreement) and continued denial of RDP to biopharmaceuticals.

CHILE

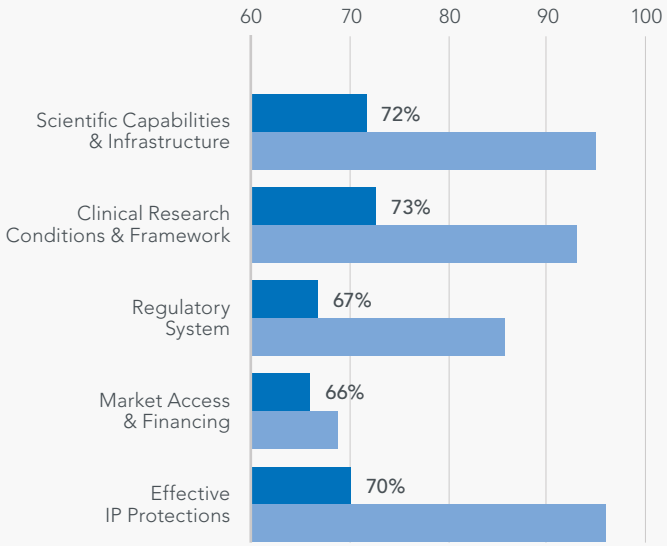
BCI Survey 2017 – Overall Scores

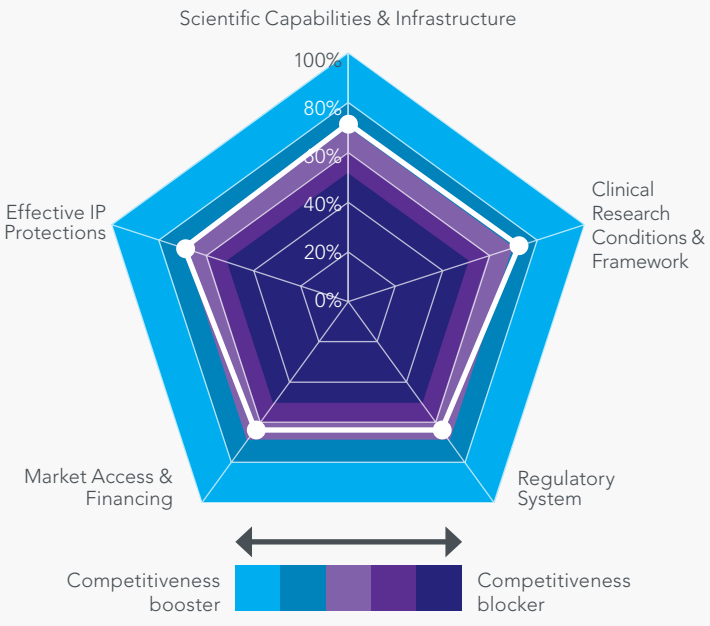
Comparison to Newcomer Markets





BCI Survey 2017 – Category Scores





Chile, % of total possible score
Top scorer, Newcomer Markets (Singapore), % of total possible score
Chile

BCI Results In Depth: What helps and what hinders Chile's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

✔ Despite a per capita R&D spending below the OECD average, executives see resources being invested strategically and consistent with an overall plan to turn Chile into a regional R&D hub.

✔ While biopharmaceutical R&D partnerships and infrastructure are considered nascent, they are seen as developing steadily.

Clinical Research Conditions & Framework

✔ Respondents rate the clinical trial environment fairly highly, with good CRO infrastructure and streamlined approval process, though the main hospitals and clinics are seen as lacking clinical research centers.

✘ Some aspects of the recent "Ricarte Soto" law (including lengthy sponsor liability) have created significant uncertainty, with executives voicing concern that it may hamper investment in clinical research.

The Regulatory System

✔ Executives rate positively the regulatory environment, noting high regulatory standards relating to biopharmaceuticals, and welcome the fact that Chile is seeking to become a Level 4 PAHO/WHO accredited regional authority.

✘ Concerns remain, however, over what are considered to be low approval standards for biosimilars.

Market Access & Financing

✘ Respondents report that heavy discounts negotiated in public tenders by CENABAST weigh down investment attractiveness.

✔ Executives are optimistic about efforts to increase the level and scope of funding for high-cost treatments under the Ricarte Soto Law, as well as what they consider an openness to value-based models by the health regulator.

Effective Intellectual Property Protections

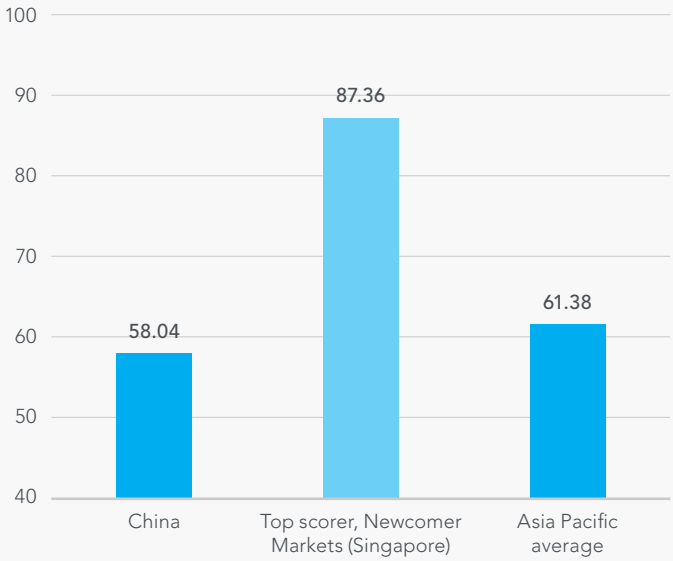
✘ Respondents view slow implementation of RDP and the recent threat of compulsory licensing based on pricing considerations as hindering an otherwise promising national efforts to turn Chile into a hub of innovation.

✔ The patenting process is viewed fairly strongly, with executives welcoming the Patent Prosecution Highway with ProSur and hiring of additional skilled examiners.

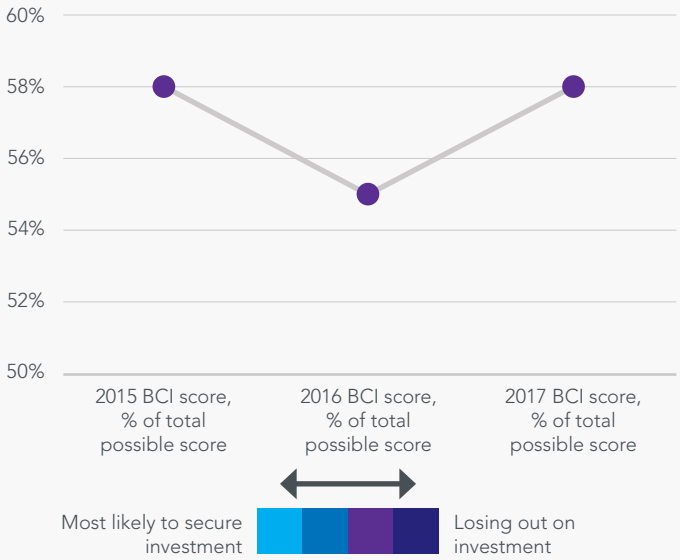
CHINA

BCI Survey 2017 – Overall Scores

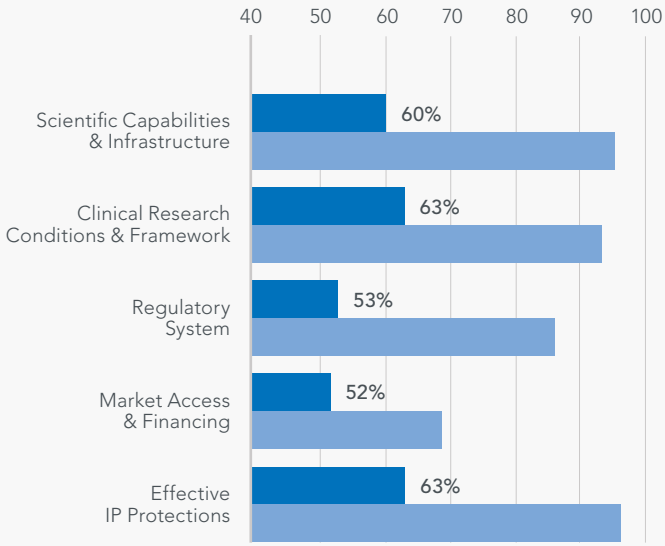
Comparison to Newcomer Markets



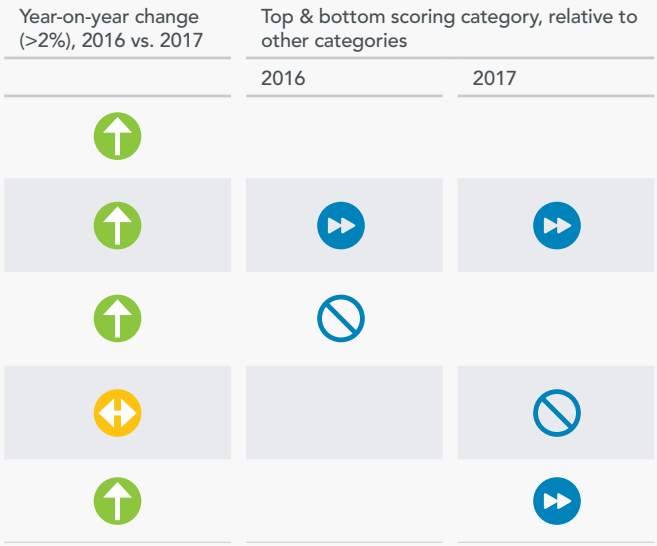
2015-2017



BCI Survey 2017 – Category Scores



China, % of total possible score
Top scorer, Newcomer Markets (Singapore), % of total possible score



Score rose · Score remained the same (<2% change in score) · Score fell
Top scoring category (LOW indicates a top scoring category <60% or where significant challenges remain) · Bottom scoring category

BCI Results In Depth: What helps and what hinders China's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

✔ Biopharmaceutical R&D capabilities are perceived as advancing quickly.

✘ Executives note the need for more support for public-private collaboration, including easing licensing conditions and commercialization activity.

Clinical Research Conditions & Framework

✔ The overall capacity for clinical research is viewed as fairly developed.

✘ Long approval timelines and complexity of regulations remain major challenges in executives' view, though new measures by the CFDA may improve the clinical research framework dramatically.

The Regulatory System

✘ Gaps in quality control and very substantial delays in new drug approval (which worsened in 2016) are viewed slightly more positively, though still emphasized as major drawbacks by executives as of the time the survey was conducted.

✔ Some challenges may be addressed by CFDA measures (if implemented), including in relation to acceptance of foreign clinical trial data, priority review and post-marketing surveillance.

Market Access & Financing

✘ Local executives highlight strict limits on prices in reimbursement and public tenders and lack of transparency (including uncertainty over the potential link to drug registration) as still hampering China's competitiveness.

Effective Intellectual Property Protections

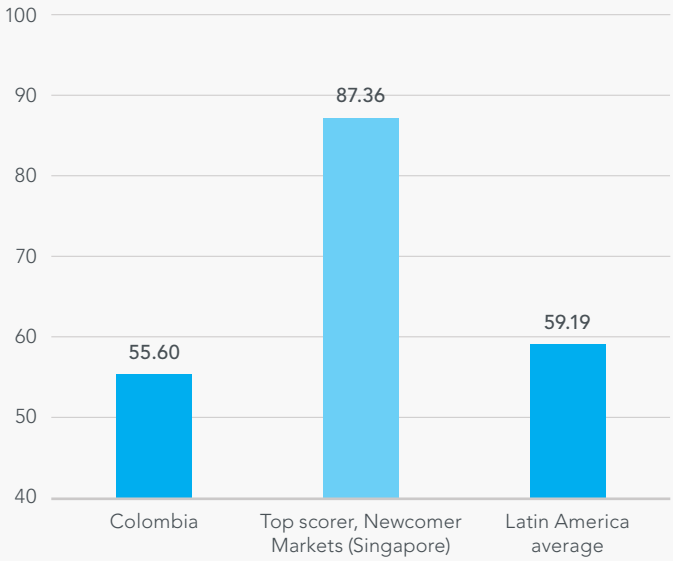
✘ Lack of clarity on RDP, patent linkage, biopharmaceutical patentability, and enforcement, which worsened in 2016, are viewed with some improvement in 2017, though still (at the time the survey was conducted) as crucial disadvantages.

✔ Major strides in these areas, particularly in relation to RDP and patent linkage, may occur under newly proposed reforms.

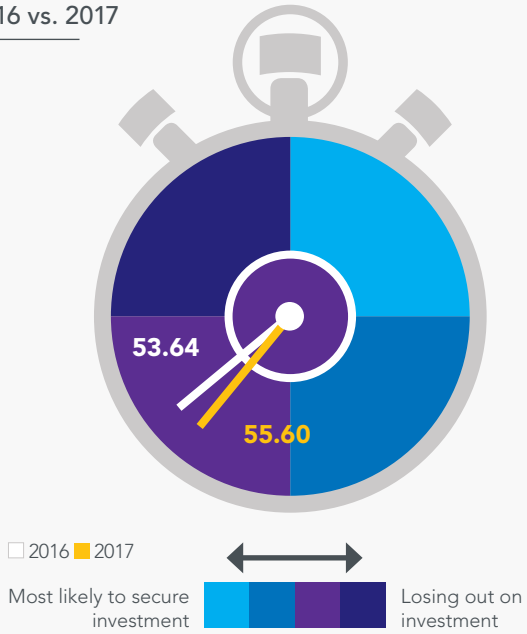
COLOMBIA

BCI Survey 2017 – Overall Scores

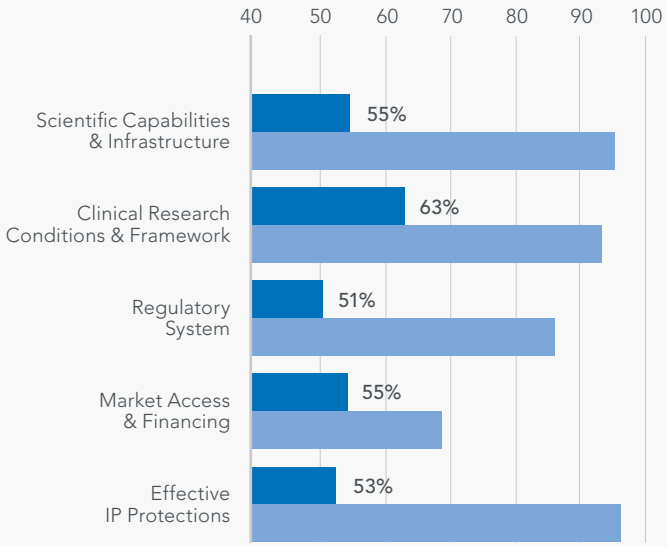
Comparison to Newcomer Markets



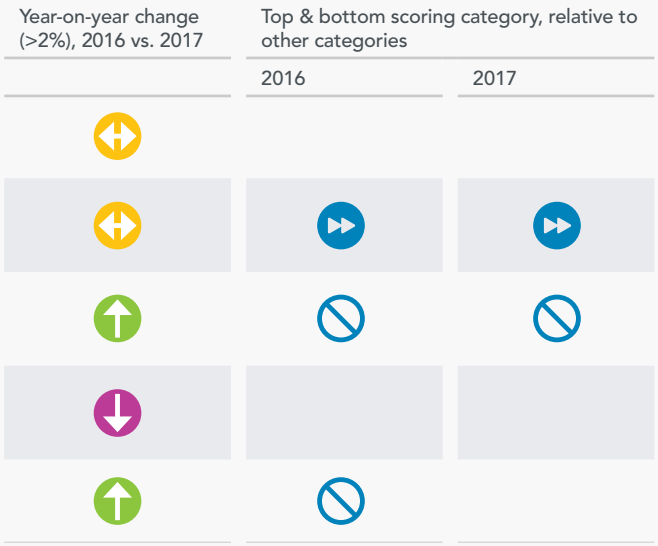
2016 vs. 2017



BCI Survey 2017 – Category Scores



Colombia, % of total possible score
Top scorer, Newcomer Markets (Singapore), % of total possible score



Score rose · Score remained the same (<2% change in score) · Score fell
Top scoring category (LOW indicates a top scoring category <60% or where significant challenges remain) · Bottom scoring category

BCI Results In Depth: What helps and what hinders Colombia's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✘ Current scientific research infrastructure is still considered sub-standard, though the government's commitment to training highly-skilled professionals in its National Development Plan 2014-2018 is viewed positively.
- ✘ Executives indicate that while some collaboration with industry takes place between high level educational and research institution, very few have tangible results.

Clinical Research Conditions & Framework

- ✔ Respondents report a growing level of clinical research capabilities among hospitals and CROs.
- ✔ Executives note that recent adherence to ICH standards and streamlined timeframes for clinical trial approval has already attracted several global CROs, though deterioration in other aspects of the biopharmaceutical environment could detract from this growth.

The Regulatory System

- ✘ While executives cite a slight improvement in regulatory timelines, they largely still view INVIMA as bureaucratic and under-staffed and the regulatory process as lacking transparency.
- ✘ Consensus exists among executives that the abbreviated "third pathway" for follow-on biologics is creating uncertainty with regards to the quality, safety and efficacy of medicines.

Market Access & Financing

- ✘ Respondents view as counterproductive current policies attempting to achieve significant price cuts and reimbursement limits.
- ✘ Executives also warn that more extreme price control measures, including the threat of using compulsory licensing and the public interest declaration route outlined in 2016/17, can in the long-run undermine any headway achieved in other areas.

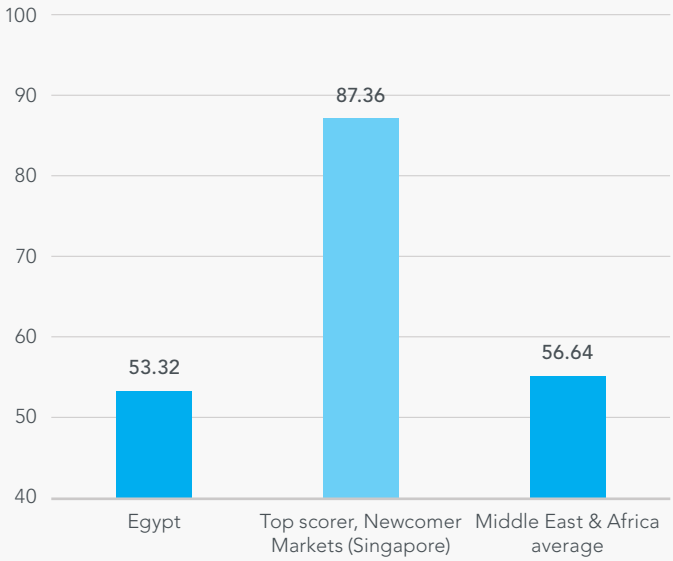
Effective Intellectual Property Protections

- ✘ Though executives' views of the biopharmaceutical IP environment improved slightly in 2017 (mainly in relation to the availability of RDP, at least for new chemical entities), overall they still note that significant improvements are needed.
- ✘ Lack of effective patent enforcement and INVIMA's potential role in patent examination are seen as greatly weakening the biopharmaceutical ecosystem.

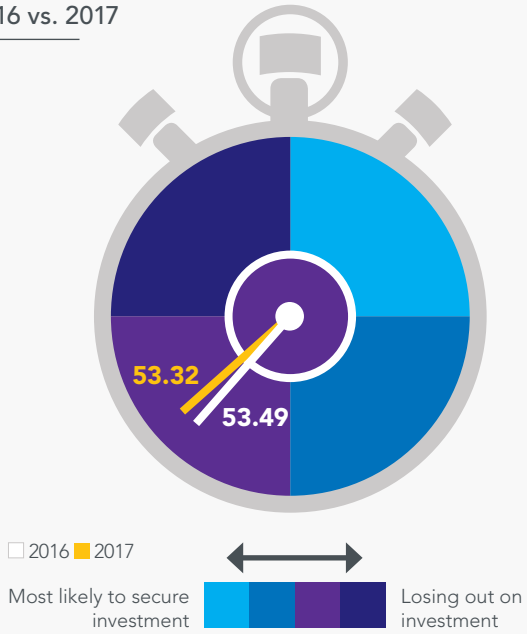
EGYPT

BCI Survey 2017 – Overall Scores

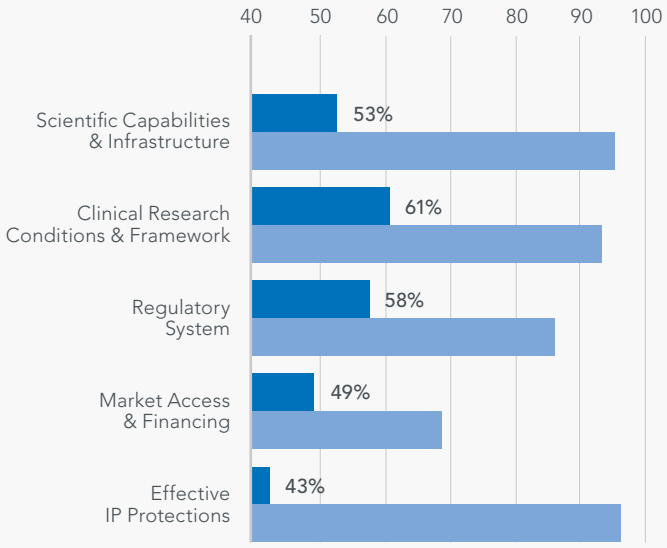
Comparison to Newcomer Markets



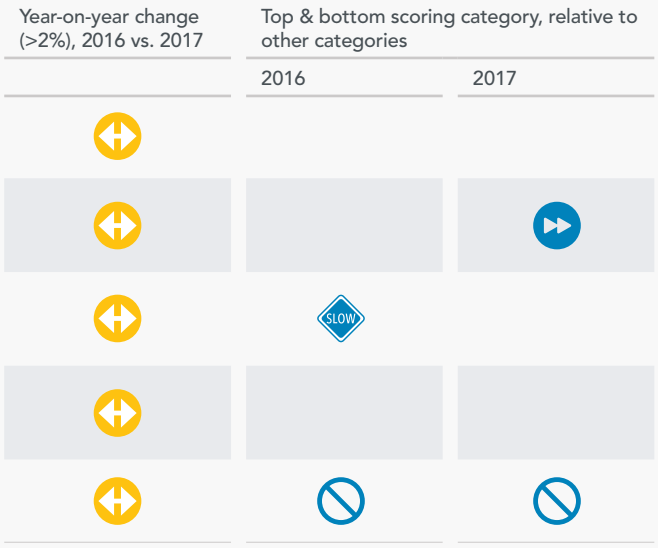
2016 vs. 2017



BCI Survey 2017 – Category Scores



Egypt, % of total possible score
Top scorer, Newcomer Markets (Singapore), % of total possible score



Score rose · Score remained the same (<2% change in score) · Score fell
Top scoring category (SLOW indicates a top scoring category <60% or where significant challenges remain) · Bottom scoring category

BCI Results In Depth: What helps and what hinders Egypt's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ The level of scientific training is seen as relatively strong.
- ✘ Executives indicate that biopharmaceutical R&D capacity remains at a basic level and collaborative initiatives limited.

Clinical Research Conditions & Framework

- ✘ Clinical trial approval timelines and gaps in clinical research capabilities among hospitals are cited as key barriers to investment in clinical trials.
- ✔ At the same time, costs of clinical research and what is considered to be a fairly strong level of compliance with international clinical standards are viewed as highly competitive compared to other newcomer markets.

The Regulatory System

- ✘ Executives view the regulatory system as at a basic level, with limited technical capacity for review of new medicines and biosimilars, though they are encouraged by a recent commitment by the Ministry of Health to introduce a fast-track approval pathway for drugs already approved by the FDA or EMA.
- ✘ The pharmacovigilance framework continues to be cited as a strength of the regulatory system.

Market Access & Financing

- ✘ Low rates of reimbursement and stringent price controls applied to innovative medicines are rated as some of the most significant impediments to investment.
- ✘ Executives also note a limited ability to participate in price negotiations.

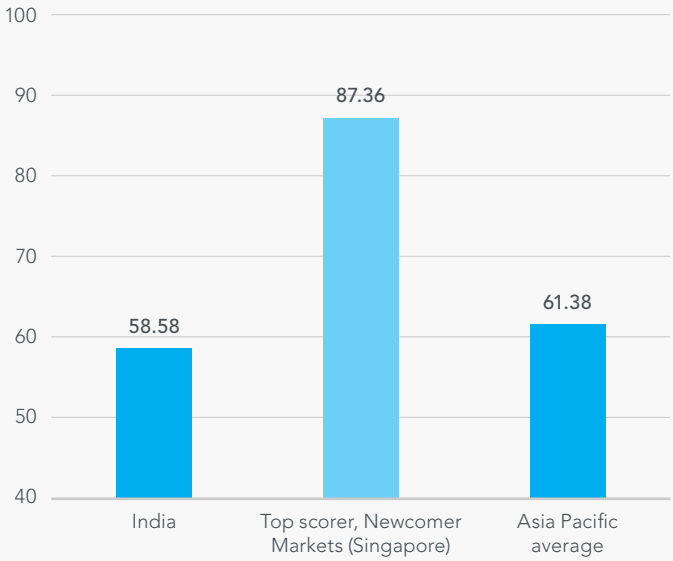
Effective Intellectual Property Protections

- ✘ Lack of basic biopharmaceutical IP rights and very limited remedies available for infringement severely hamper Egypt's competitiveness.
- ✘ The patenting process is viewed as bureaucratic, with a low level of technical expertise.

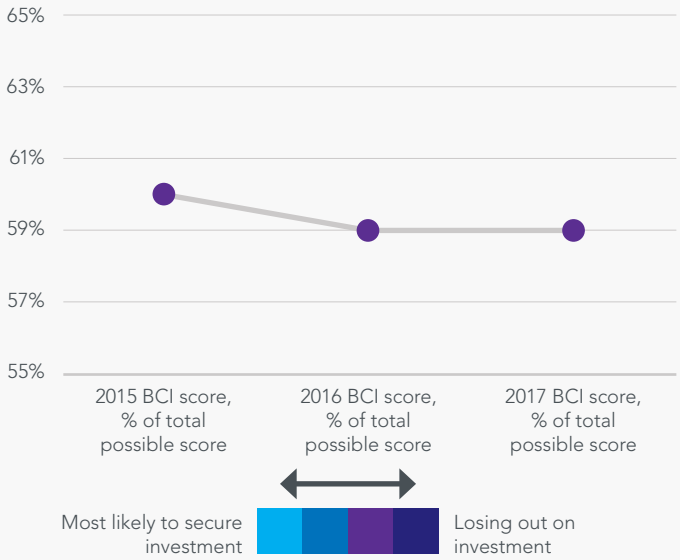
INDIA

BCI Survey 2017 – Overall Scores

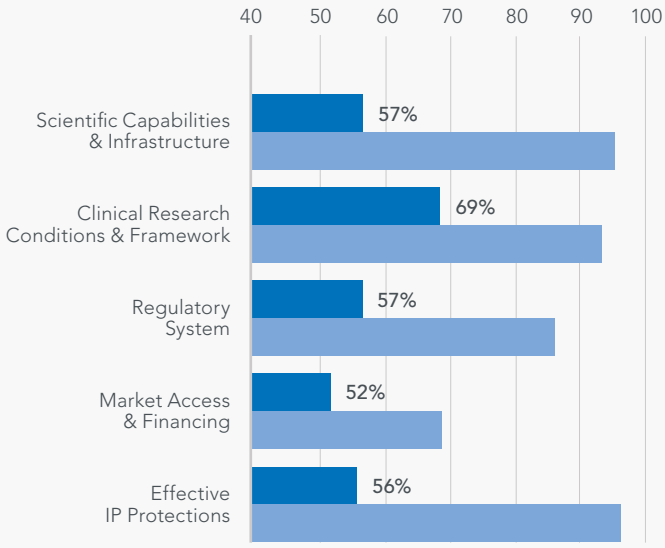
Comparison to Newcomer Markets



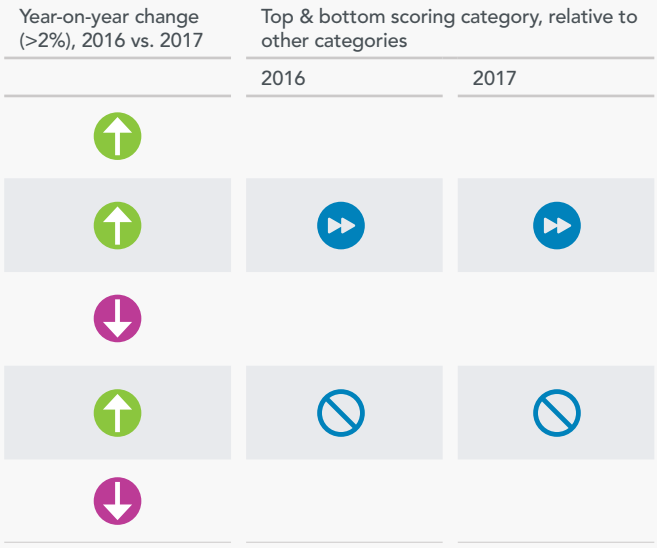
2015-2017



BCI Survey 2017 – Category Scores



India, % of total possible score
Top scorer, Newcomer Markets (Singapore), % of total possible score



Score rose · Score remained the same (<2% change in score) · Score fell

Top scoring category (LOW indicates a top scoring category <60% or where significant challenges remain) · Bottom scoring category

BCI Results In Depth: What helps and what hinders India's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

✘ Weak infrastructure and resources for biopharmaceutical R&D limit technology transfer, although recent plans by the DIPP to create Technology and Innovation Support Centers are welcome.

✔ Executives regard growing availability of highly qualified researchers as a key strength that should be better leveraged.

Clinical Research Conditions & Framework

✔ Executives note that ongoing efforts to make clinical research regulations more predictable have aided in improving the environment but a recent proposal to introduce a local trial requirement could unravel these strides.

✔ Relatively strong clinical research capabilities and competitive costs are mentioned among the key strengths of the Indian clinical trial framework.

The Regulatory System

✔ Drug review capacity among regulatory authorities is regarded as adequate though inconsistent across regions.

✘ Long delays in drug approval and gaps in quality control and post-marketing are even more at the forefront of executives' minds in 2017, though they also note that the environment is evolving.

Market Access & Financing

✘ Executives view efforts to streamline drug regulation as positive, but insufficient. The ongoing threat of price controls expansion (such as price caps and greater use of INN in reimbursement) perpetuates an unpredictable business environment and is seen as stifling India's innovation potential while leaving the main barriers to drug access unaddressed.

✘ Respondents regard the reimbursement framework as inadequate and highlight the need to expand coverage to low-income populations and not only seek to achieve low prices for NLEM medicines.

Effective Intellectual Property Protections

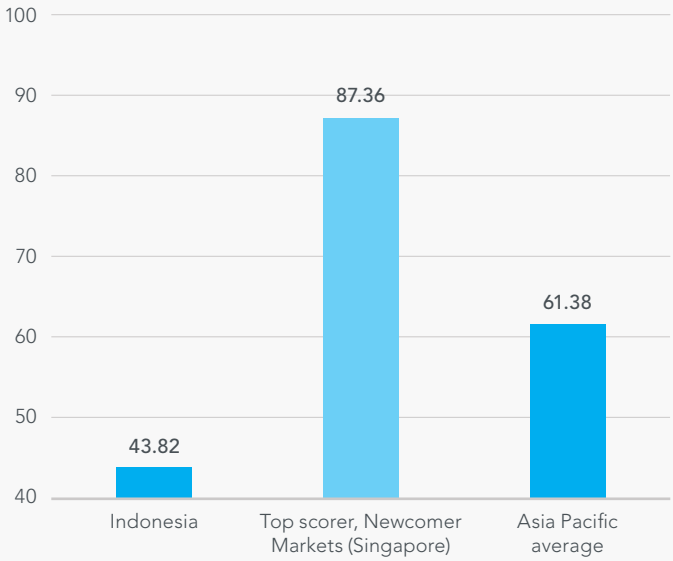
✘ Respondents view the level of biopharmaceutical IP protection as stagnating, with forward progress undermined by a continued unwillingness to assure protections that do exist.

✘ Although the National IP Rights Policy promised to address the issue, enforcement of IP rights continues to be perceived as seriously inadequate.

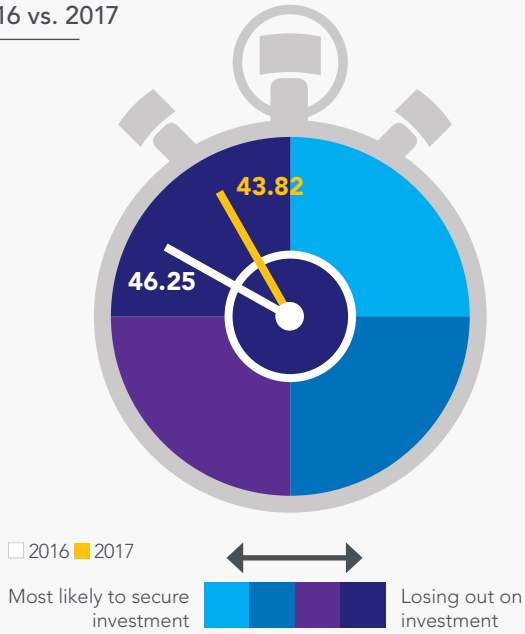
INDONESIA

BCI Survey 2017 – Overall Scores

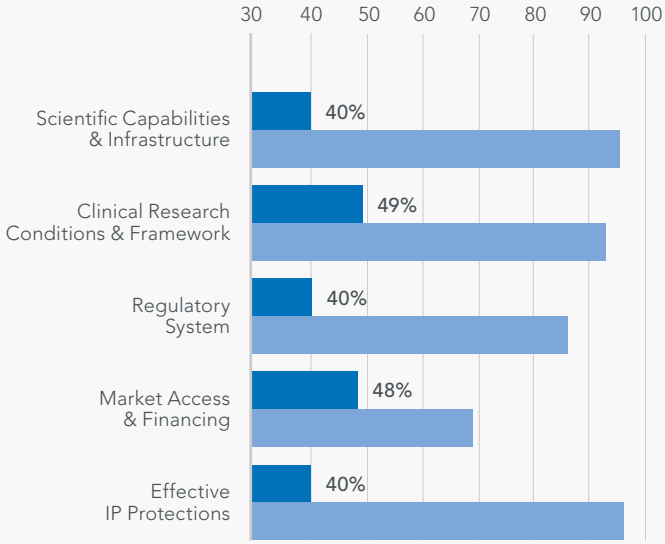
Comparison to Newcomer Markets

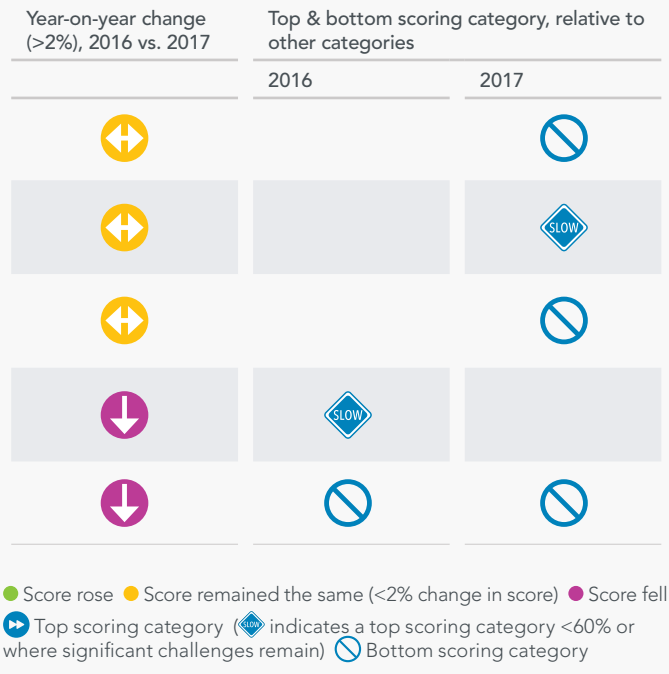


2016 vs. 2017



BCI Survey 2017 – Category Scores





BCI Results In Depth: What helps and what hinders Indonesia's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✘ Capabilities for biopharmaceutical R&D are regarded as undeveloped and the need for advanced scientific training noted.
- ✘ Executives cite a low level of collaboration between academia and industry (with the exception of select clinical trials), further impeded by new requirements for forced technology of patented medicines.

Clinical Research Conditions & Framework

- ✘ Though some interest in clinical research exists, inadequate local capacity for conducting and managing clinical trials among hospitals and CROs, and lack of government incentives and regulatory standards, are viewed as holding back investment.
- ✘ Very significant delays around trial approval are noted.

The Regulatory System

- ✘ Regulatory capacity and processes are overwhelmingly perceived as inadequate and out-of-sync with international standards (including requirements for Halal certification which are seen as adding significant cost and risk for biopharmaceutical companies in terms of burden of compliance and potential sharing of confidential commercial information).
- ✘ Drug approval timelines are noted as some of the longest among newcomer markets.

Market Access & Financing

- ✘ Market access conditions are viewed poorly, with discrimination of foreign and innovative medicines accelerating.
- ✘ The lack of predictable pricing and reimbursement rules is also mentioned as an element of strong concern.

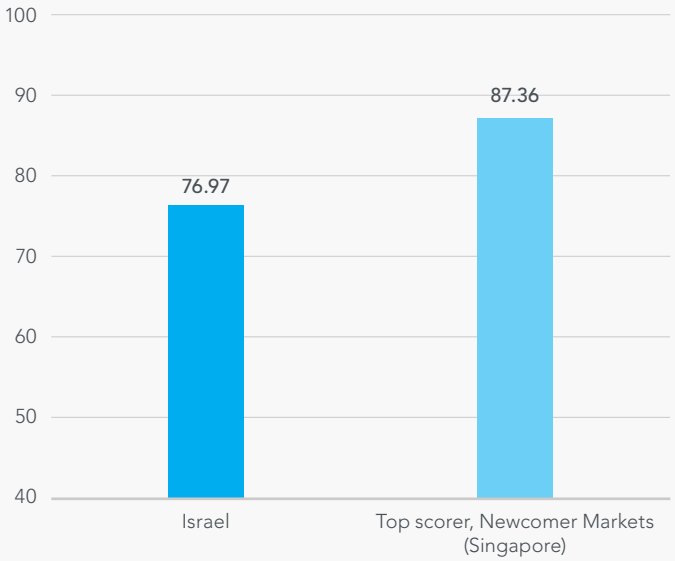
Effective Intellectual Property Protections

- ✘ The IP environment is viewed as increasingly challenging and driving Indonesia's lack of competitiveness, with recent amendments to the IP law notably denying certain types of biopharmaceutical patents and expanding the basis for compulsory licensing.
- ✘ Lack of effective enforcement of biopharmaceutical patents and other IP rights is also a major concern.

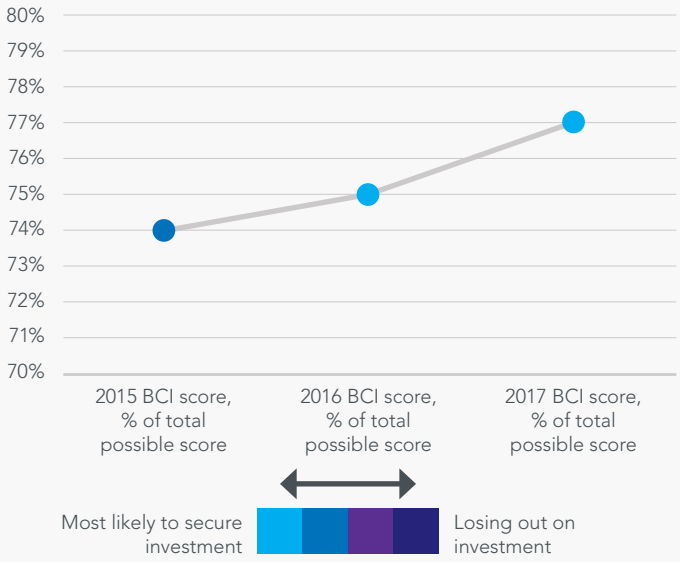
ISRAEL

BCI Survey 2017 – Overall Scores

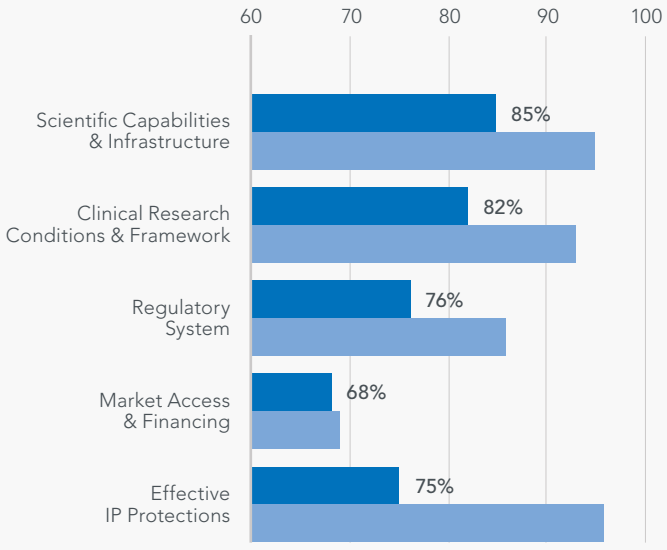
Comparison to Newcomer Markets



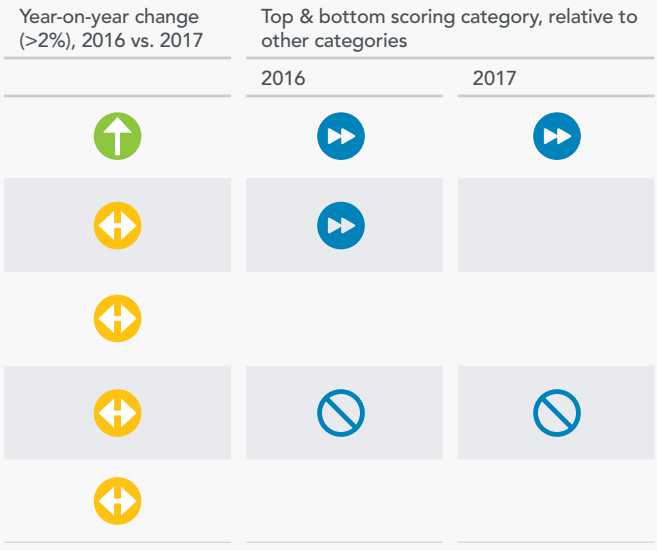
2015-2017



BCI Survey 2017 – Category Scores



Israel, % of total possible score
Top scorer, Newcomer Markets (Singapore), % of total possible score



Score rose
Score remained the same (<2% change in score)
Score fell
Top scoring category (LOW indicates a top scoring category <60% or where significant challenges remain)
Bottom scoring category

BCI Results In Depth: What helps and what hinders Israel's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ Marked progress noted in establishing top quality life science education, research centers, and infrastructure.
- ✔ Though room for improvement still remains, executives cite an enhanced level of connectedness of research centers with industry.

Clinical Research Conditions & Framework

- ✔ Clinical research conditions are viewed as highly supportive, driving some of the highest per capita rates of clinical research globally.
- ✘ Relatively high costs and delays in trial approval compared to other newcomer markets hold Israel back from achieving an even higher rate of clinical trials.

The Regulatory System

- ✔ Overall capacity for drug review is viewed as fairly strong and in line with international standards, but further strengthening is needed in the field of pharmacovigilance.
- ✘ Respondents also emphasized bottlenecks in drug registration as a key area for improvement.

Market Access & Financing

- ✘ The pricing and reimbursement environment remains mixed in executives' perspective, especially due to continued price pressure and lack of transparency in the reimbursement process, though a significant increase in the annual budget for drug reimbursement in 2017 is welcomed.
- ✔ Access to biopharmaceutical innovation is considered relatively wide and timely under supplementary insurance schemes.

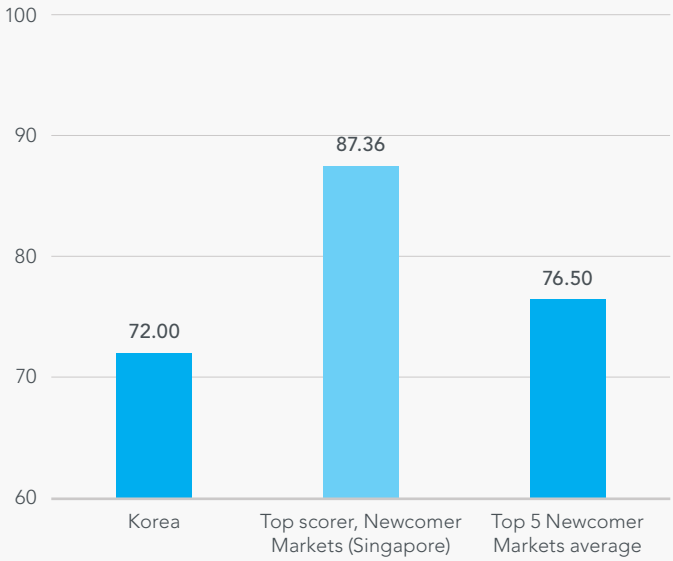
Effective Intellectual Property Protections

- ✔ The biopharmaceutical IP environment, including the presence of several key life sciences IP rights, is viewed as being of a relatively high standard, with even further enhancing of the patenting process under proposed reforms.
- ✘ Respondents note that the lack of RDP for biologics (at the time of the survey) and uncertainties in relation to enforcement of biopharmaceutical patents remain substantial hurdles hindering Israel's competitiveness.

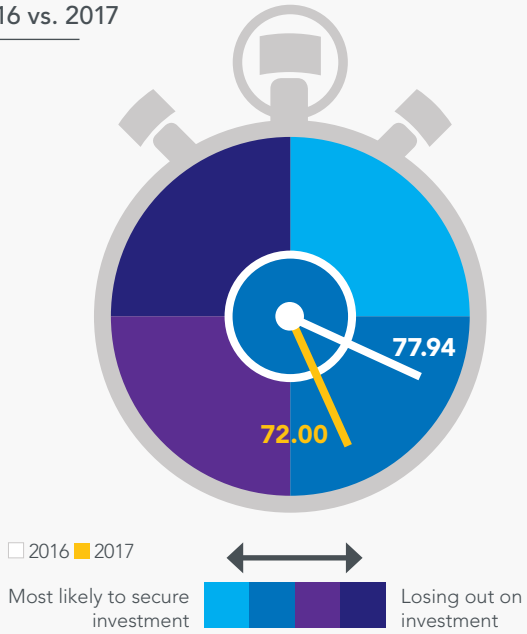
KOREA

BCI Survey 2017 – Overall Scores

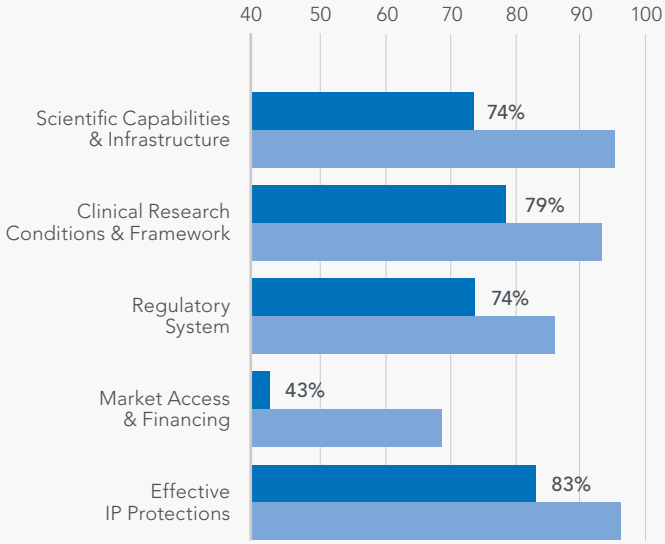
Comparison to Newcomer Markets



2016 vs. 2017



BCI Survey 2017 – Category Scores



Korea, % of total possible score
Top scorer, Newcomer Markets (Singapore), % of total possible score

Year-on-year change (>2%), 2016 vs. 2017	Top & bottom scoring category, relative to other categories	
	2016	2017
↔		
↓		
↓		
↓	⊘	⊘
↓	⏩	⏩

Score rose · Score remained the same (<2% change in score) · Score fell

⏩ Top scoring category (LOW indicates a top scoring category <60% or where significant challenges remain) ⊘ Bottom scoring category

BCI Results In Depth: What helps and what hinders Korea's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ Overall, scientific capabilities are perceived positively by executives, notably the presence of qualified researchers and well-developed infrastructure.
- ✘ Still, executives see room to improve collaboration between public R&D entities and multinational pharmaceutical companies.

Clinical Research Conditions & Framework

- ✔ Executives regard clinical trial conditions as being supportive, though approval timelines are seen as requiring further streamlining.
- ✔ Clinical research infrastructure is viewed as top-notch, with what are considered some of the most advanced IT systems and ICT infrastructure available to domestic CROs.

The Regulatory System

- ✔ The regulatory environment is cited as fairly strong, with further improvements to the management of advanced biopharmaceuticals, such as cell therapy products, announced in 2017.
- ✔ Market approval and post-marketing monitoring of medicines is considered to be on par with developed market standards, although speedier approval could aid in making the country more attractive.

Market Access & Financing

- ✘ Very stringent and arbitrary price controls and limits on public reimbursement are regarded as having a grave impact on competitiveness, and diluting optimism of executives in other areas.
- ✘ Executives mention recent pricing rules discriminating against foreign innovative and biosimilar companies as a further challenge to market access.

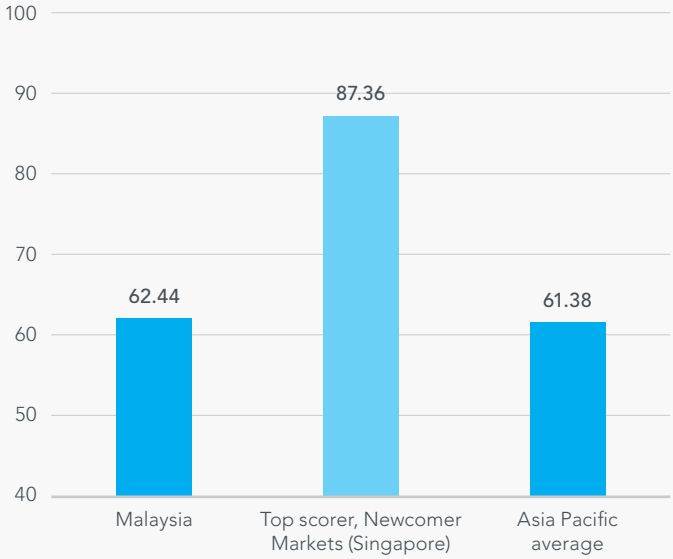
Effective Intellectual Property Protections

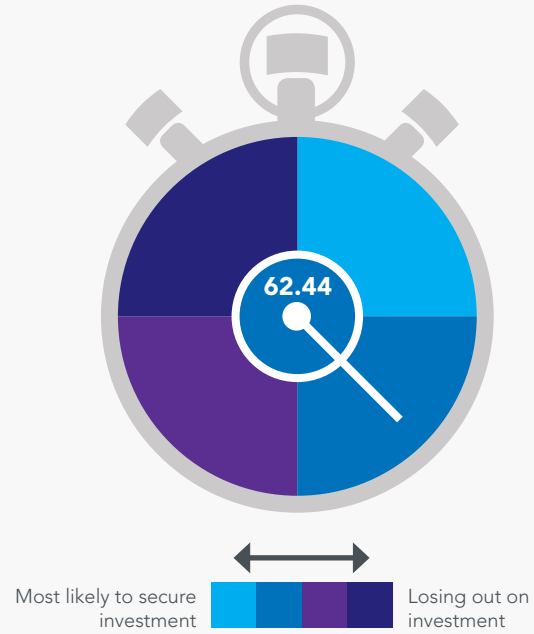
- ✔ The level of biopharmaceutical IP protection is regarded as relatively strong, and recent commitments to further enhancing areas such as patent processing (through amendments to the Patent Law) welcome.
- ✘ While enforcement of IP rights is generally regarded as reasonable, uncertainty exists around practical recognition by drug regulators of biopharmaceutical patents and RDP. A recent court decision has undermined the value of patent term extension.

MALAYSIA

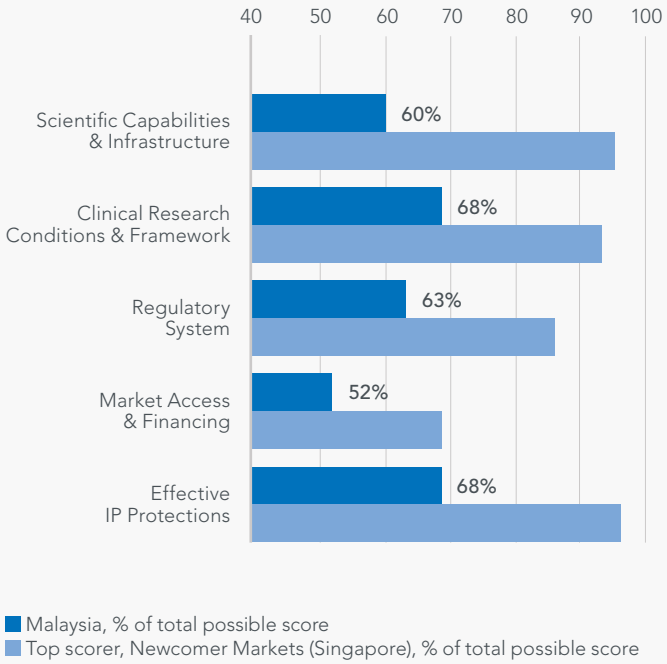
BCI Survey 2017 – Overall Scores

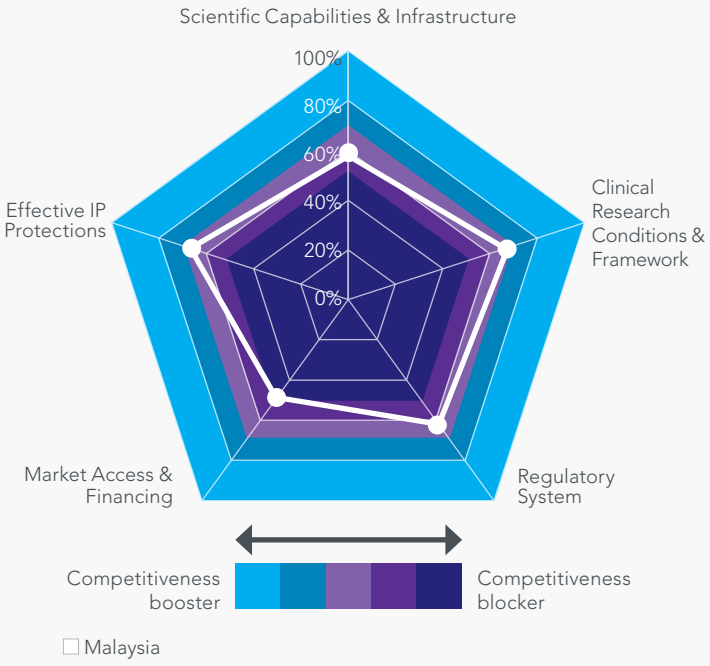
Comparison to Newcomer Markets





BCI Survey 2017 – Category Scores





BCI Results In Depth: What helps and what hinders Malaysia's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ The level of scientific education and training is viewed as being relatively advanced compared to many other newcomer markets.
- ✘ However, executives see capabilities for biopharmaceutical R&D specifically as underdeveloped and not improving, and opportunities for collaborating with public institutions as mixed.

Clinical Research Conditions & Framework

- ✔ The clinical research environment is seen as a relative strength, with strong clinician interest and some government support (such as through the Clinical Research Center within the Ministry of Health), but not properly leveraged due to gaps in wider biopharmaceutical R&D conditions.
- ✔ Conducting clinical trials in the country is considered to be relatively low cost.

The Regulatory System

- ✔ Basic drug review capacity is seen as in place, although with room for improvement.
- ✘ Executives note delays in obtaining marketing approval and gaps in quality control as two major challenges.

Market Access & Financing

- ✘ Executives identify lack of clear and predictable reimbursement criteria, limited scope of reimbursement and long listing delays as major barriers to investment.
- ✔ Private insurance schemes are viewed as playing an important role in supporting access to needed treatments, with a public health insurance scheme still in the process of being introduced.

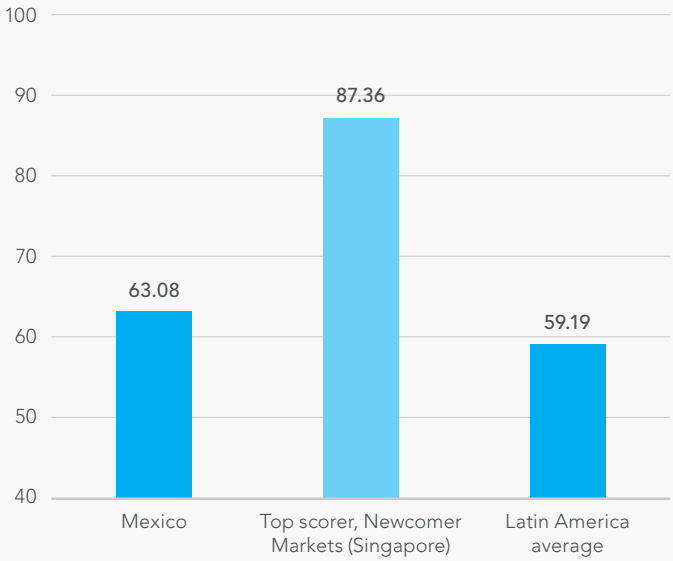
Effective Intellectual Property Protections

- ✔ Overall, basic IP standards are seen as being in place, though Malaysia is missing key biopharmaceutical IP rights and the available rights are sometimes seen as favoring local producers.
- ✘ Executives note the lack of an effective regulatory patent enforcement system and potential threat of compulsory licensing as two important challenges. Malaysia's recent decision to compulsory license an innovative medicine will add significantly to industry concerns.

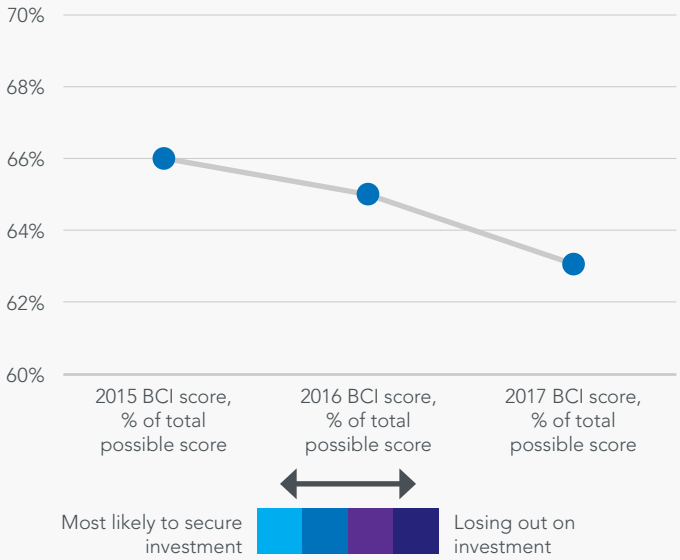
MEXICO

BCI Survey 2017 – Overall Scores

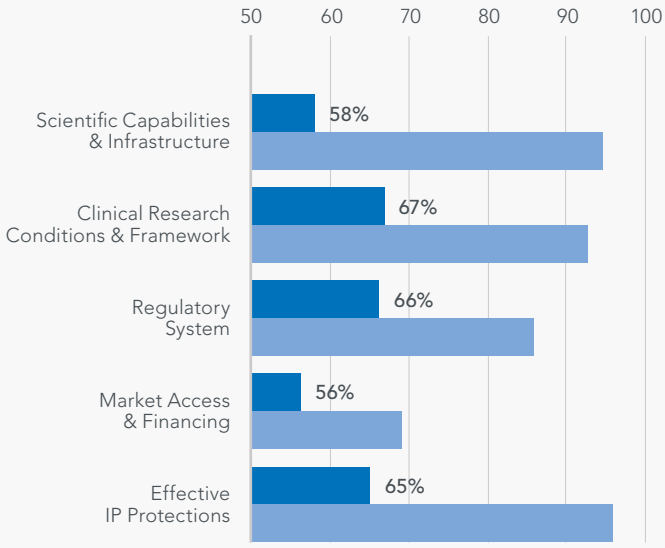
Comparison to Newcomer Markets

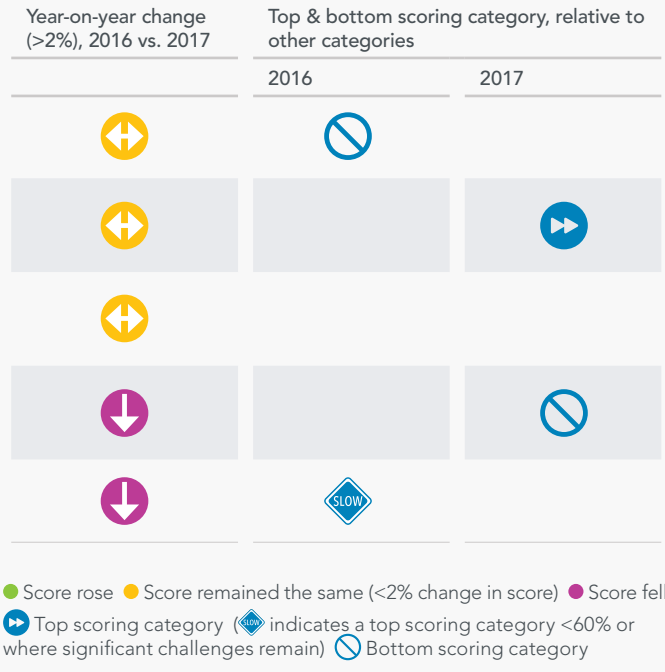


2015-2017



BCI Survey 2017 – Category Scores





BCI Results In Depth: What helps and what hinders Mexico's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ Research infrastructure continues to be substandard, although respondents are encouraged by Mexico's stated commitment to develop world-class scientific capabilities, which has translated into concrete and significant public R&D spending.
- ✘ Collaboration between industry and research institutions remains uneven, and is based largely on the policies in place at the institution receiving the public funding.

Clinical Research Conditions & Framework

- ✔ Respondents are largely optimistic about Mexico's efforts to attract clinical research, noting that several healthcare systems (with millions of subscribers) are opening for clinical trial activity. Clinical trials in Mexico are seen as cost-efficient and in line with international standards, despite gaps in capacity for clinical research.
- ✔ Streamlining the clinical trial approval process is reportedly yielding positive results (displaying a drop of 2 months), although respondents note there is still room for improvement.

The Regulatory System

- ✔ Executives are encouraged by COFEPRIS' new policies to significantly cut delays in drug approvals, from 360 days to 60 days and what are considered to be relatively strong approval standards for biologics.
- ✔ A grass-roots pharmacovigilance mindset is considered as an opportunity for collaboration between industry, COFEPRIS and other stakeholders.

Market Access & Financing

- ✘ Respondents call worrisome a perceived lack of transparency in decision-making and preferential treatment of local companies in public tenders.
- ✘ Executives mention that public pricing and reimbursement is primarily focused on cost and drug formularies under the major public schemes all contain relatively low levels of innovative drugs.

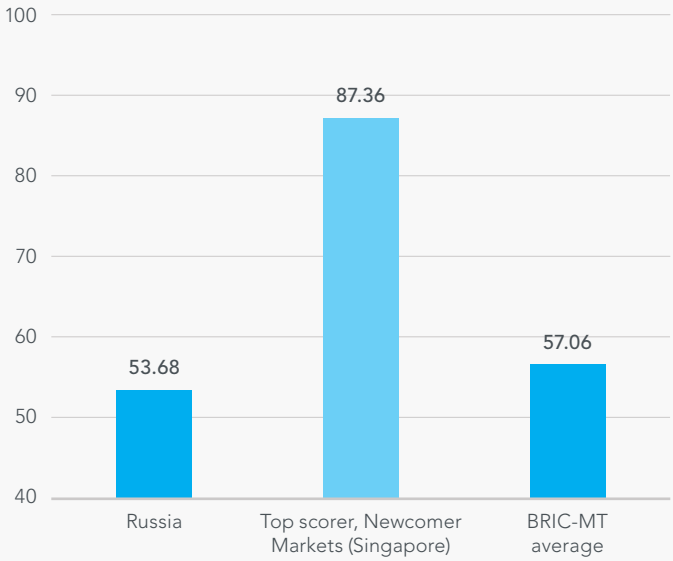
Effective Intellectual Property Protections

- ✔ Respondents are generally encouraged by Mexico's efforts to improve its IP environment, though they note the uneven application of RDP and patent linkage to biologics and certain types of biopharmaceutical innovations.
- ✘ Uncertainty over the future of biopharmaceutical IP protection under re-negotiated trade agreements and deep budgetary cuts to IP courts is one concern of executives.

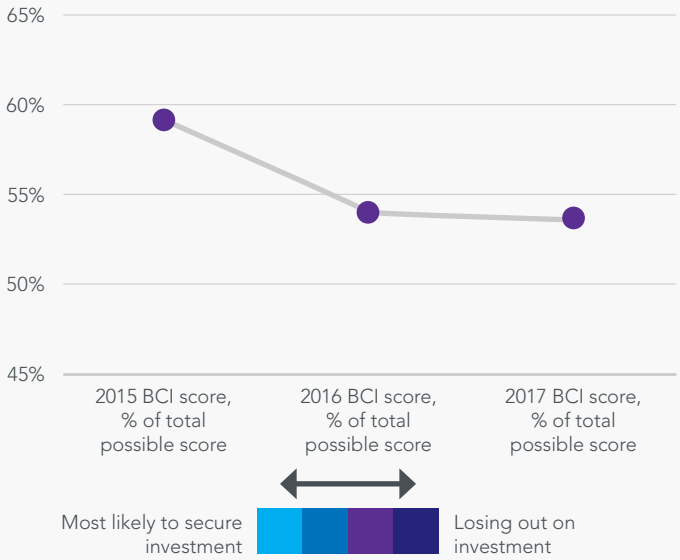
RUSSIA

BCI Survey 2017 – Overall Scores

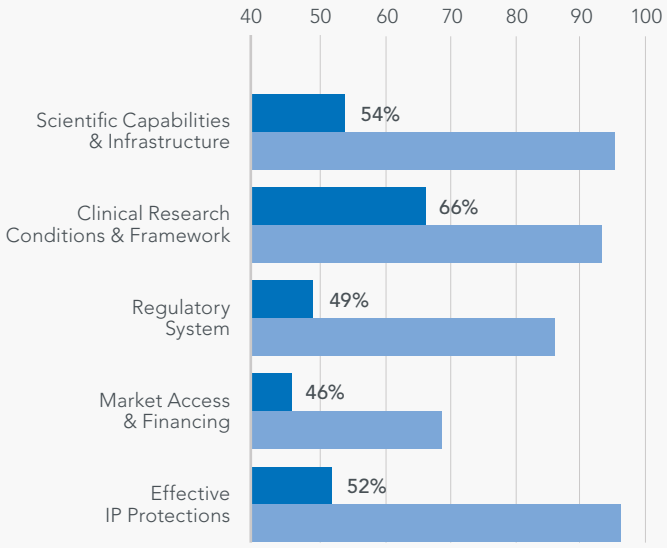
Comparison to Newcomer Markets



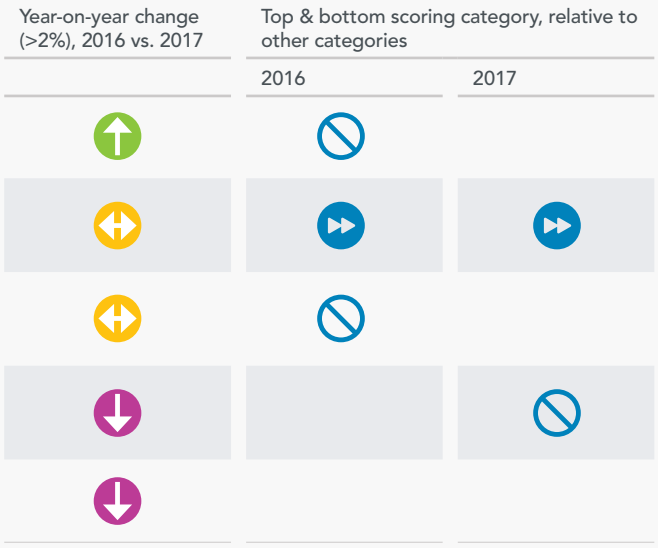
2015-2017



BCI Survey 2017 – Category Scores



Russia, % of total possible score
Top scorer, Newcomer Markets (Singapore), % of total possible score



Score rose
Score remained the same (<2% change in score)
Score fell
Top scoring category (LOW indicates a top scoring category <60% or where significant challenges remain)
Bottom scoring category

BCI Results In Depth: What helps and what hinders Russia's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✘ Though scientific education and training is rated slightly higher in 2017 (following several years of attempting to strengthen the level of scientific training) executives continue to regard specific R&D capabilities for the field of biopharmaceuticals as basic.
- ✘ The growth of new science parks is seen as promising for increasing the low level of collaboration with local R&D entities, but thus far concrete R&D investment and licensing has not followed in kind (with other conditions, such as localization requirements, hampering R&D investment incentives).

Clinical Research Conditions & Framework

- ✔ Executives view major hospitals as willing and increasingly well equipped to conduct high standard clinical trials.
- ✘ However, bottlenecks in the regulatory system and wider conditions preferencing local companies hinder cutting edge clinical research from taking off in Russia.

The Regulatory System

- ✘ Executives continue to view Russia's regulatory capacity as below par, in spite of recent efforts to improve regulation of biologics and biosimilars.
- ✔ GMP compliance is viewed as having improved somewhat, but compliance still varies considerably and executives remain concerned about the risk of substandard medicines.

Market Access & Financing

- ✘ The ongoing trend of favoring domestic products in public tenders and granting monopoly to state companies is increasingly cited as discouraging and, ironically, one of the foremost barriers to investment.
- ✘ A potential deterioration of the pricing environment (including recent discussion of price caps and a "world's lowest" target for prices) is seen as further threatening investment.

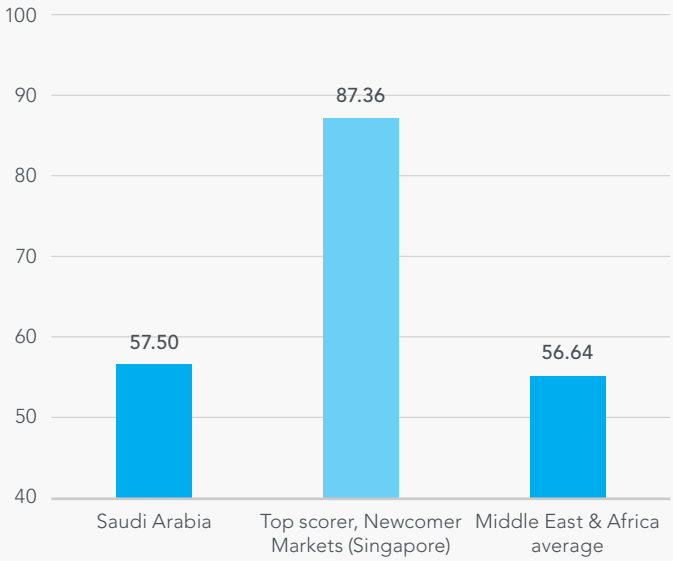
Effective Intellectual Property Protections

- ✘ The lack of effective patent protection and enforcement, and the uncertainty it creates for innovators, is also a major detractor, viewed very weakly by executives compared to other newcomer markets.
- ✔ Nevertheless, executives welcome the recent PPH pilot program between ROSPATENT and the EPO.

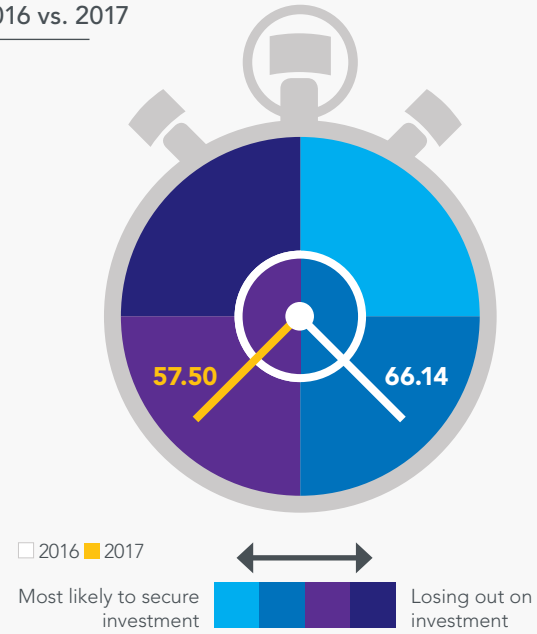
SAUDI ARABIA

BCI Survey 2017 – Overall Scores

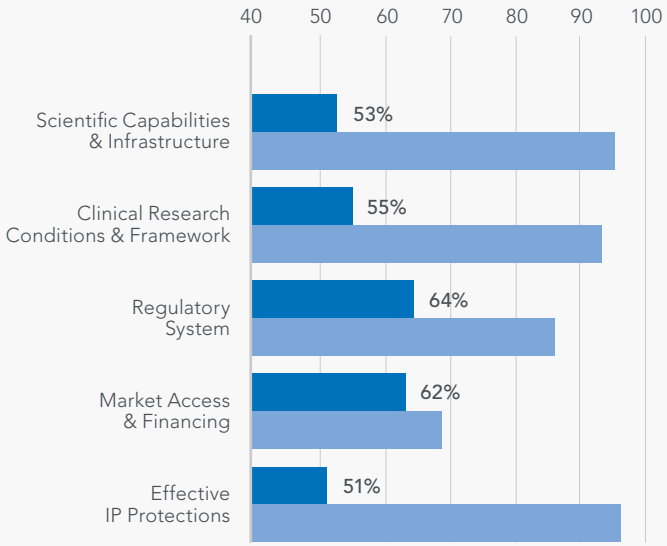
Comparison to Newcomer Markets

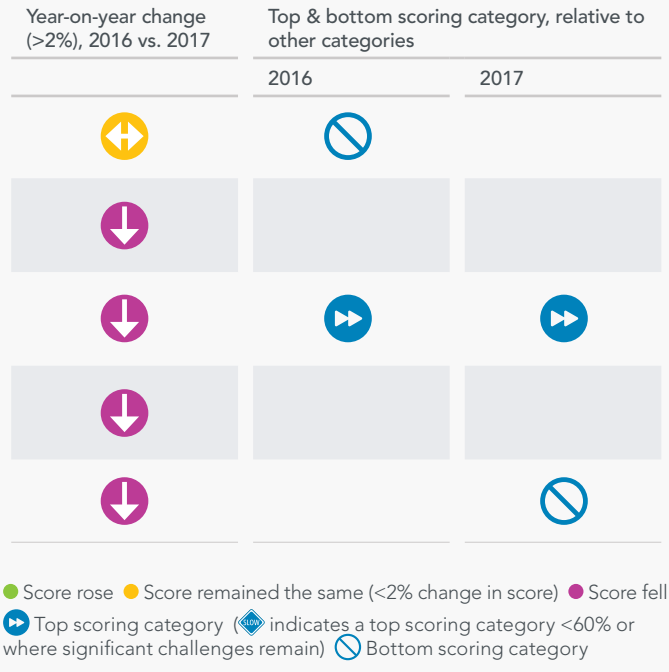


2016 vs. 2017



BCI Survey 2017 – Category Scores





BCI Results In Depth: What helps and what hinders Saudi Arabia's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ Though the level of public-private research collaboration is regarded as limited to a few major institutions, executives view as a positive signal a recent government push for building partnerships.
- ✘ Executives continue to see R&D capabilities as nascent and needing further development if they are to support local biopharmaceutical R&D.

Clinical Research Conditions & Framework

- ✘ While clinical research capacity is accelerating and the governing framework improving, activity is noted as still limited mainly to Phase III trials.
- ✘ Working through local public research organizations presents some challenges for companies.

The Regulatory System

- ✔ Executives are pleased with significant improvement to approval timelines (down to 6-12 months), with additional advances expected under an announced fast-track verification route for innovative drugs.
- ✘ Though the SFDA is viewed as upholding generally high regulatory standards, executives point to the need to improve review capacity for biosimilars and to streamline pharmacovigilance and reporting procedures.
- ✘ Executives are also highly discouraged by recent instances in which IP rights were not recognized in the approval of follow-on products.

Market Access & Financing

- ✘ Executives view pricing and reimbursement decisions as lacking clear guidelines and favoring low-cost or domestic products.
- ✔ The scope and depth of reimbursement coverage for innovative drugs is generally perceived as adequate.

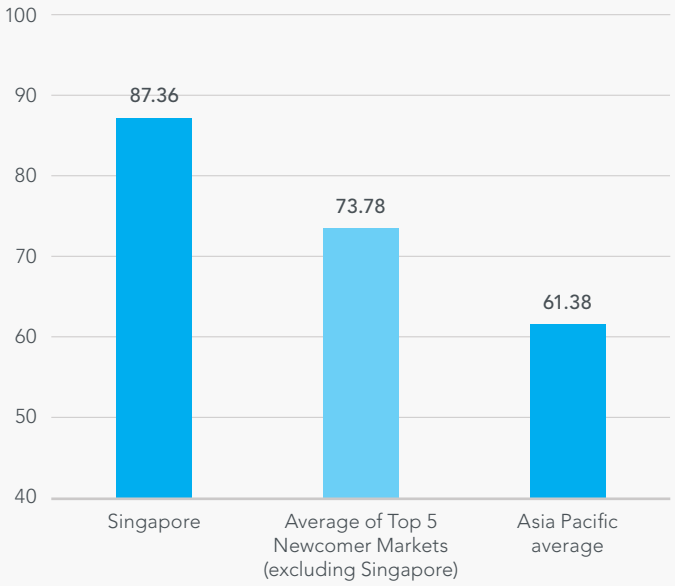
Effective Intellectual Property Protections

- ✘ Executives are deeply concerned over what they consider to be a growing disregard by local authorities for biopharmaceutical IP rights provided for in Saudi law, significantly downgrading biopharmaceutical investment conditions across the board.
- ✘ Particular challenges lie in implementing the existing regulatory patent enforcement mechanism and RDP, both of which have been considered in the past as key strengths of the Saudi IP environment.

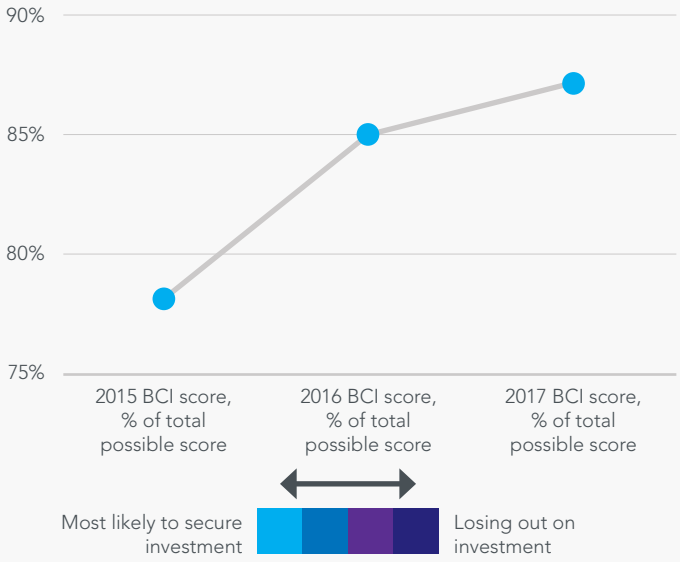
SINGAPORE

BCI Survey 2017 – Overall Scores

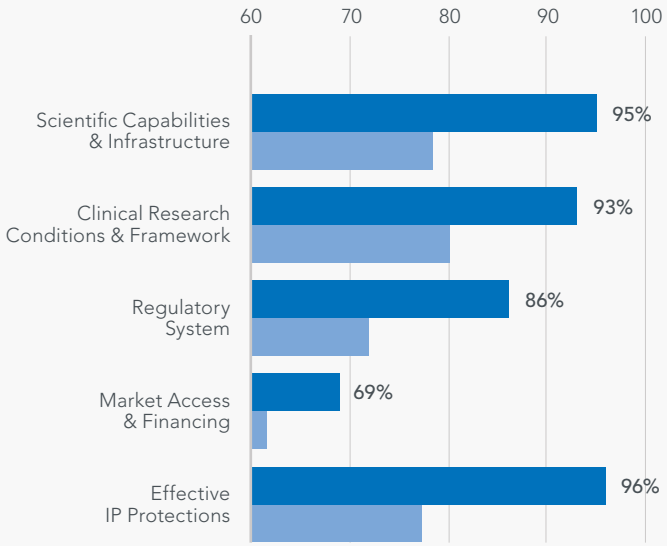
Comparison to Newcomer Markets



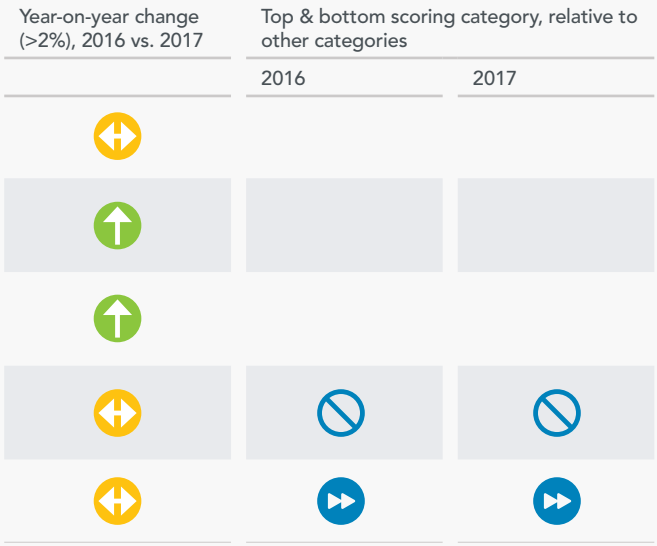
2015-2017



BCI Survey 2017 – Category Scores



Singapore, % of total possible score
Average of Top 5 Newcomer Markets (excluding Singapore), % of total possible score



Score rose · Score remained the same (<2% change in score) · Score fell
Top scoring category (LOW indicates a top scoring category <60% or where significant challenges remain) · Bottom scoring category

BCI Results In Depth: What helps and what hinders Singapore's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ Sustained and growing government investment in human skills, technology transfer and advanced manufacturing capacity through industry partnerships is regarded as a key strength.
- ✔ Executives view the level of collaboration in the area of clinical research positively, but identify partnerships with academic centers focusing on basic research as an area that could be strengthened.

Clinical Research Conditions & Framework

- ✔ Confidence in clinical research conditions continues to grow, on the back of further efforts to enhance what is already seen as a highly supportive and high standard environment.
- ✘ Though the speed of clinical trial approval overall is seen as quite good, if executives could identify a weakness it would lie in what is considered to be a slow ethics committee procedure.

The Regulatory System

- ✔ The biopharmaceutical regulatory framework is viewed as enforcing rigorous standards and set to be upgraded even further, thanks to additional government push for international standardization and platforms for cooperation and capacity building.
- ✔ The rate and speed of approval of innovative drugs is seen as another strength.

Market Access & Financing

- ✔ Supplementary and private coverage schemes for reimbursement of medicines are considered to improve access to cutting edge treatments.
- ✘ Executives note that greater transparency of pricing and reimbursement decisions would enhance the country's attractiveness.

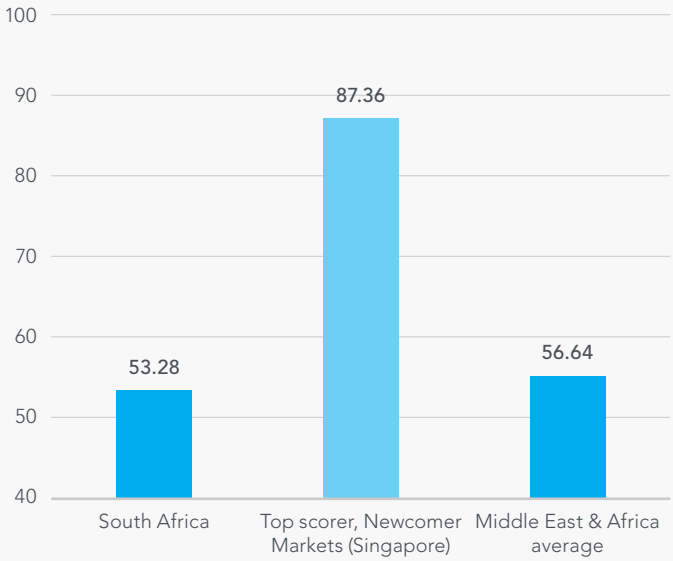
Effective Intellectual Property Protections

- ✔ Robust biopharmaceutical IP standards are seen as being in place and applied in practice.

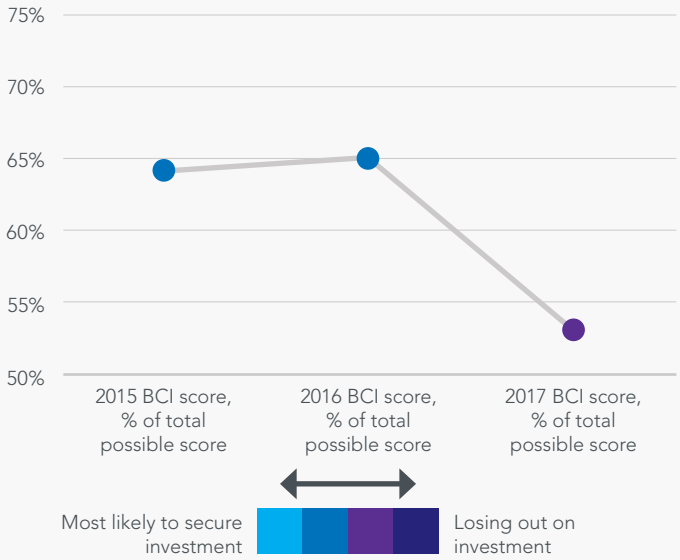
SOUTH AFRICA

BCI Survey 2017 – Overall Scores

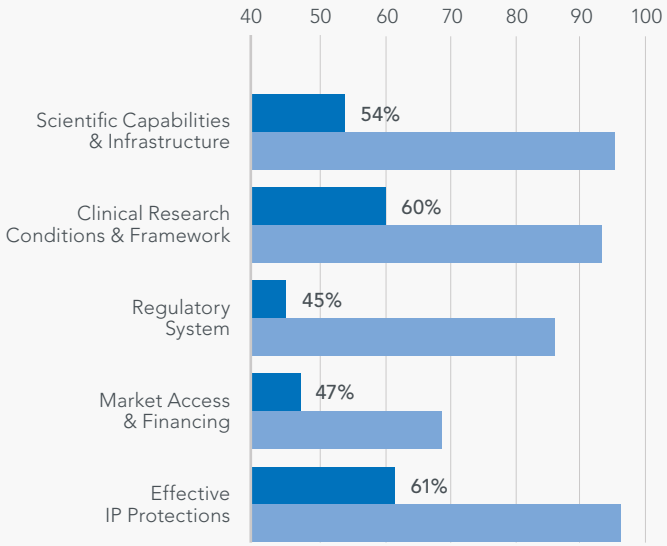
Comparison to Newcomer Markets



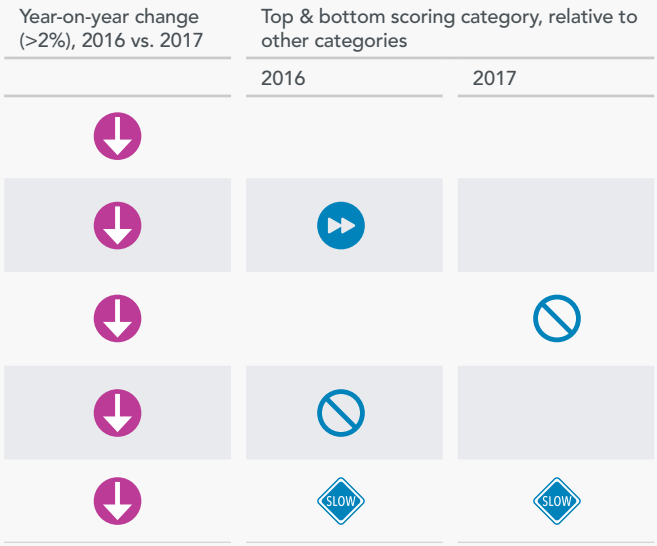
2015-2017



BCI Survey 2017 – Category Scores



South Africa, % of total possible score
Top scorer, Newcomer Markets (Singapore), % of total possible score



Score rose Score remained the same (<2% change in score) Score fell
Top scoring category (SLOW indicates a top scoring category <60% or where significant challenges remain) Bottom scoring category

BCI Results In Depth: What helps and what hinders South Africa's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

✘ Executives cite growing gaps in domestic biopharmaceutical R&D capacities on the back of low and decreasing R&D investment, with most research activities focused on vaccines.

✔ The level of scientific education and training overall is regarded as adequate, and may be further strengthened by ongoing plans to upgrade the country's research infrastructure.

Clinical Research Conditions & Framework

✘ Executives mention long trial approval delays as a major barrier in domestic clinical research conditions.

✔ The level of clinical trial infrastructure, clinical research management and compliance with global clinical standards (GCP) are regarded as satisfactory.

The Regulatory System

✘ Long drug approval delays of at least five years are seen as a major detractor, and executives are highly discouraged that the creation of the new drug regulatory agency meant to address this problem has been repeatedly postponed (as of the time of the survey).

✘ Inadequate regulatory capacity, notably with regard to complex drugs, is regarded as another key impediment to investment.

Market Access & Financing

✘ Executives view heavy price restrictions and proposed benchmarking as a major damper on competitiveness.

✘ Ongoing procurement preference for local products also continues to be seen as a serious disadvantage of the market.

Effective Intellectual Property Protections

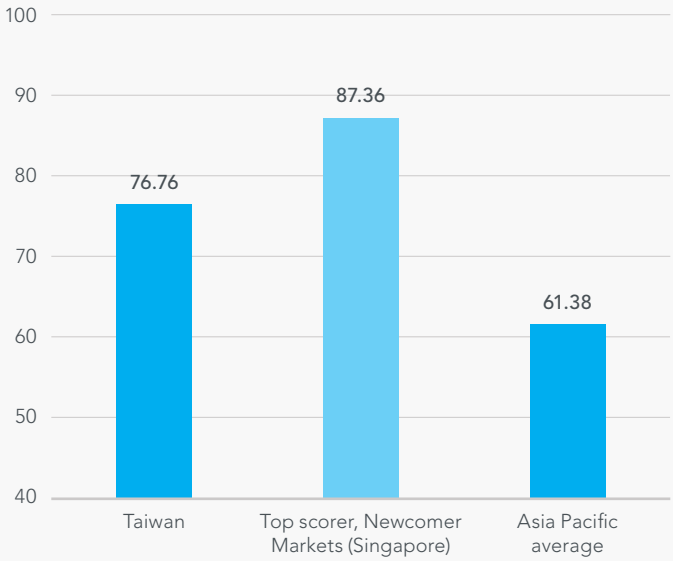
✘ Though recognized for providing a basic level of IP protection, executives identify severe gaps in biopharmaceutical rights, including effective patent enforcement.

✘ Uncertainty over the government's review of the IP system and the extent to which proposed changes to the biopharmaceutical IP regime could limit innovation is also a big damper on executives' confidence.

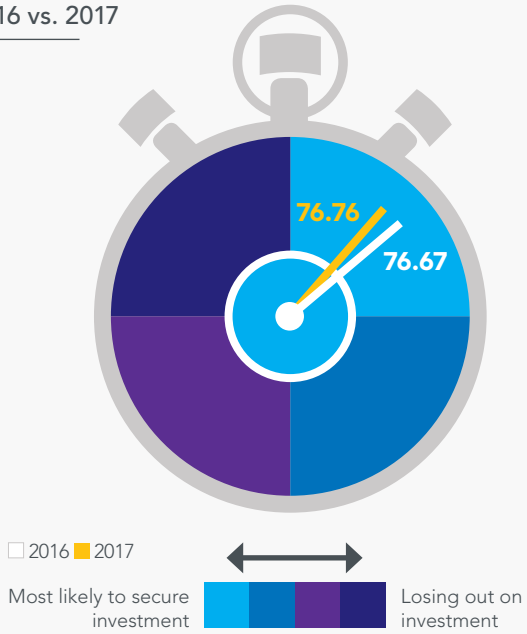
TAIWAN

BCI Survey 2017 – Overall Scores

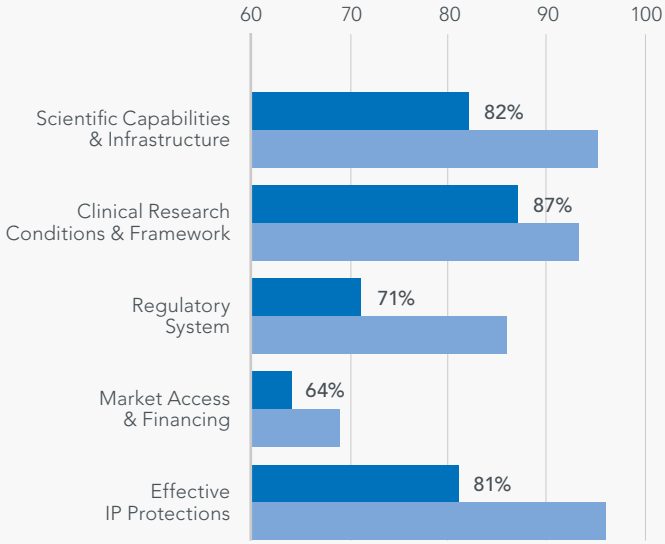
Comparison to Newcomer Markets



2016 vs. 2017



BCI Survey 2017 – Category Scores



Taiwan, % of total possible score
Top scorer, Newcomer Markets (Singapore), % of total possible score

Year-on-year change (>2%), 2016 vs. 2017	Top & bottom scoring category, relative to other categories	
	2016	2017
⇔		
⇔	⏩	⏩
⇔		
⇔	⃠	⃠
⇔		

Score rose · Score remained the same (<2% change in score) · Score fell

⏩ Top scoring category (LOW indicates a top scoring category <60% or where significant challenges remain) ⃠ Bottom scoring category

BCI Results In Depth: What helps and what hinders Taiwan's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ The biomedical science base is viewed as fairly sophisticated.
- ✔ Executives cite a good level of commercialization and technology transfer from universities and research institutes, though stronger collaboration with industry would be welcome.

Clinical Research Conditions & Framework

- ✔ Clinical research conditions are viewed as very competitive and generally in line with international best practices.
- ✔ Capacity for clinical research among hospitals and CROs is considered to be a key factor supporting Taiwan's competitiveness.

The Regulatory System

- ✔ The regulatory framework is regarded as broadly supportive, although some clarification and guidance is still required, notably for biosimilar monoclonal antibodies.
- ✘ Although generally shorter than in the past, approval delays are perceived as a key area for improvement.

Market Access & Financing

- ✘ Executives highlight what they consider to be slow and opaque reimbursement decisions shaped primarily by budgetary considerations and annual reviews of drug prices as key barriers to market access.
- ✔ Coverage of biopharmaceuticals through the public reimbursement system is perceived as a relative strength.

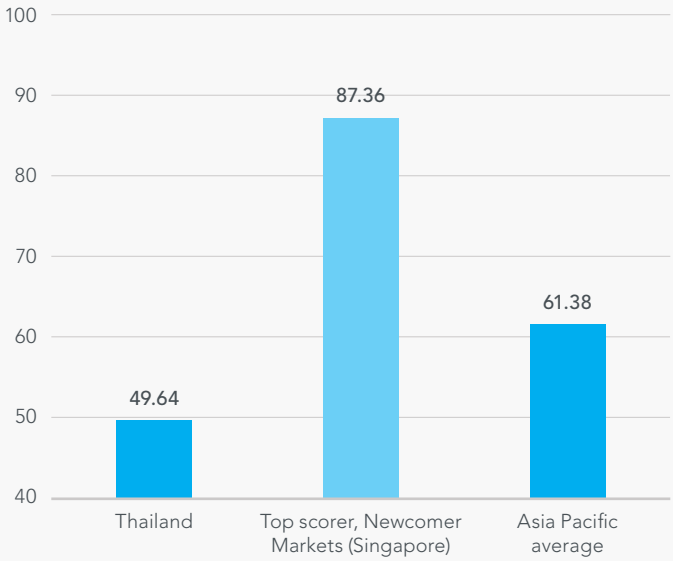
Effective Intellectual Property Protections

- ✔ Taiwan is seen as having a number of IP policy fundamentals in place, including ability to secure biopharmaceutical patents and secure civil remedies for infringement, as well as a basic level of RDP.
- ✘ However, importantly, patent linkage and RDP are regarded as sub-optimal compared to other advanced economies and executives welcome discussion on enhancing provisions in these areas in line with global best practices, such as introducing an effective patent linkage mechanism and explicitly providing RDP for biologics and new indications.

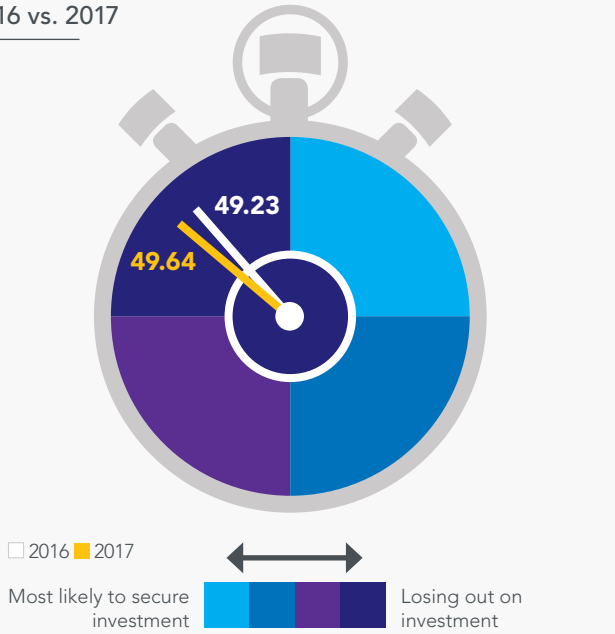
THAILAND

BCI Survey 2017 – Overall Scores

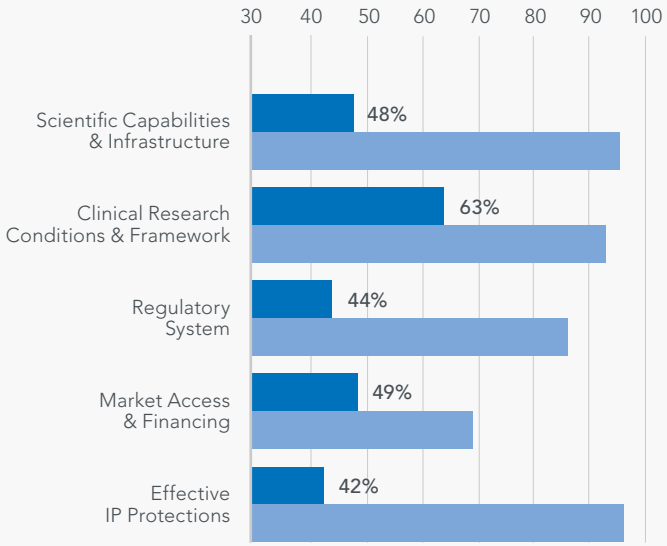
Comparison to Newcomer Markets

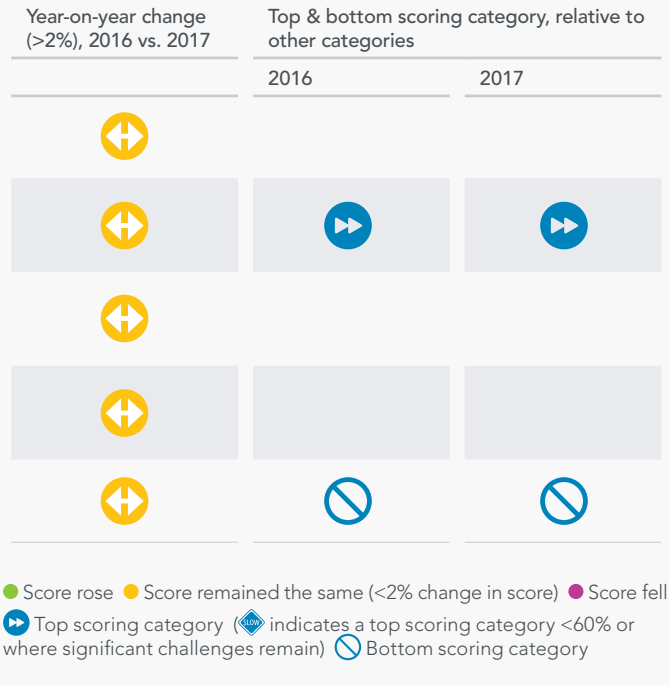


2016 vs. 2017



BCI Survey 2017 – Category Scores





BCI Results In Depth: What helps and what hinders Thailand's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

✘ Executives consider biopharmaceutical R&D capabilities as very basic, although the ongoing research policy overhaul and efforts to build medical hubs provide opportunity for concretely prioritizing the sector.

✔ Availability of skilled human capital is cited as gradually increasing, including as part of the Thailand 4.0 initiative.

Clinical Research Conditions & Framework

✔ Overall, clinical research capacity is regarded as a strength, with CROs seen as demonstrating adequate compliance with global clinical trial standards and strong interest in participation from public medical schools.

✘ Long clinical trial approval delays are seen as one key disadvantage.

The Regulatory System

✘ Regulatory capacity for review and monitoring of medicines is still perceived as behind other newcomer markets, notably in relation to innovative and biosimilar drugs.

✘ Drug approval delays are also viewed as a key barrier for innovators.

Market Access & Financing

✘ In the executives' view, arbitrary pricing & reimbursement decisions and discrimination of foreign companies in tenders continue to hamper the investment climate significantly.

✔ Gaining access to cutting-edge treatments through private reimbursement schemes is considered to be possible, though not readily available or utilized.

Effective Intellectual Property Protections

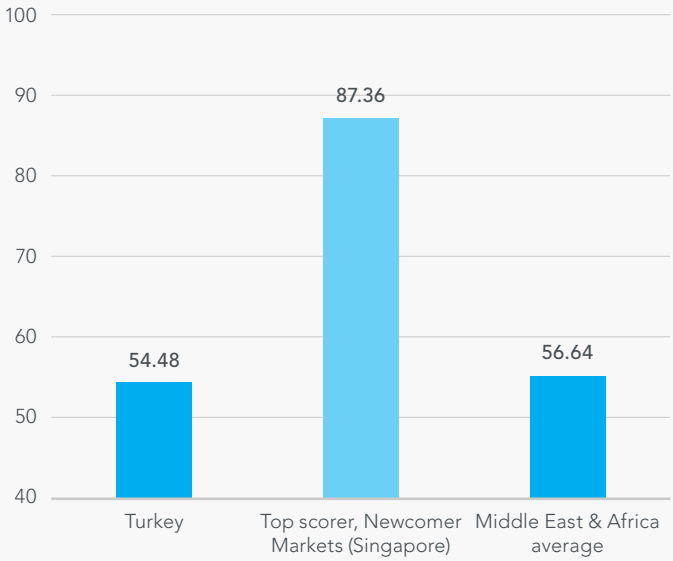
✘ Inadequate biopharmaceutical IP rights still represent major drawbacks for innovators and are viewed as severely limiting Thailand's attractiveness.

✘ Executives exhibit strong concerns over what is considered to be weak and unpredictable patent enforcement, patent review backlogs, and lack of RDP.

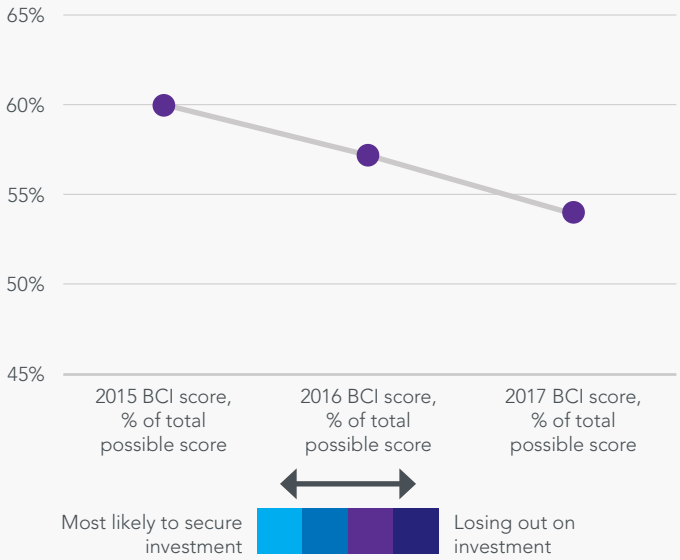
TURKEY

BCI Survey 2017 – Overall Scores

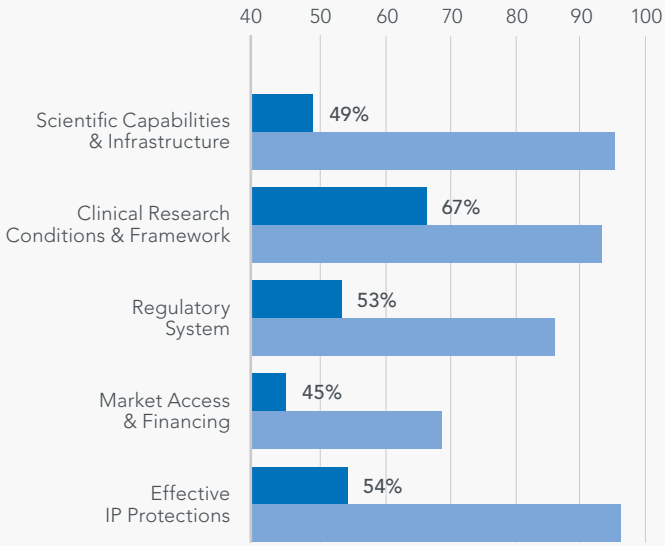
Comparison to Newcomer Markets



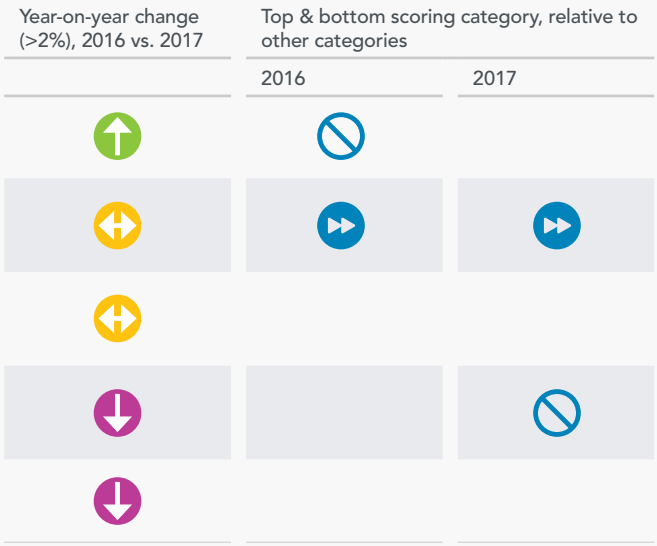
2015-2017



BCI Survey 2017 – Category Scores



Turkey, % of total possible score
Top scorer, Newcomer Markets (Singapore), % of total possible score



Score rose · Score remained the same (<2% change in score) · Score fell
Top scoring category (LOW indicates a top scoring category <60% or where significant challenges remain) · Bottom scoring category

BCI Results In Depth: What helps and what hinders Turkey's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✘ Overall the country's readiness to carry out biopharmaceutical R&D is regarded as below par, with executives noting a need for more multidisciplinary research and partnerships with industry in order to address what is considered to be a disconnect between academic research and biopharmaceutical R&D trends.
- ✘ Though displaying a slightly better outlook on technology transfer in 2017 (due particularly to ongoing efforts by the Technology Transfer Accelerator and TUBITAK), executives still note a low level of commercialization of research.

Clinical Research Conditions & Framework

- ✔ Executives refer to the presence of adequate and relatively low cost infrastructure and human resources for clinical trials as advantages.
- ✘ However, appetite for investing in clinical research can be limited due to heavy requirements placed on trial sponsors to cover all health and related drug expenses of participants.

The Regulatory System

- ✘ Executives view approval delays for innovative products, notably due to idiosyncratic GMP certification rules, as continuing to harm Turkey's attractiveness and a significant factor undermining its attempt to become a biopharmaceutical hub.
- ✘ Though capacity for quality control and pharmacovigilance is seen as fairly good, drug review capacity, especially for complex products, is seen as behind the curve.

Market Access & Financing

- ✘ Increasingly punitive market access conditions for innovators, including the start of an import substitution program in 2016, are regarded as the topmost damper on the investment climate in Turkey.
- ✘ Executives notably mention harsh price cuts and opaque reimbursement criteria as deterring innovation.

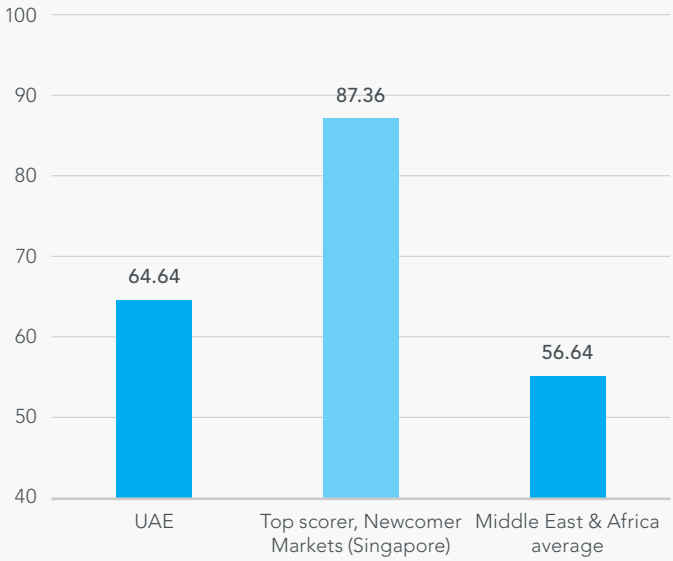
Effective Intellectual Property Protections

- ✘ Overall, IP rights and enforcement are regarded as remaining weak and the fact they were unaddressed in the recent IP law is seen as discouraging.
- ✘ Executives note that increasing discussion by the government on use of compulsory licensing, including widening the basis for issuing compulsory licenses to non-use in the new IP law, has potential to dismantle the investment environment further.

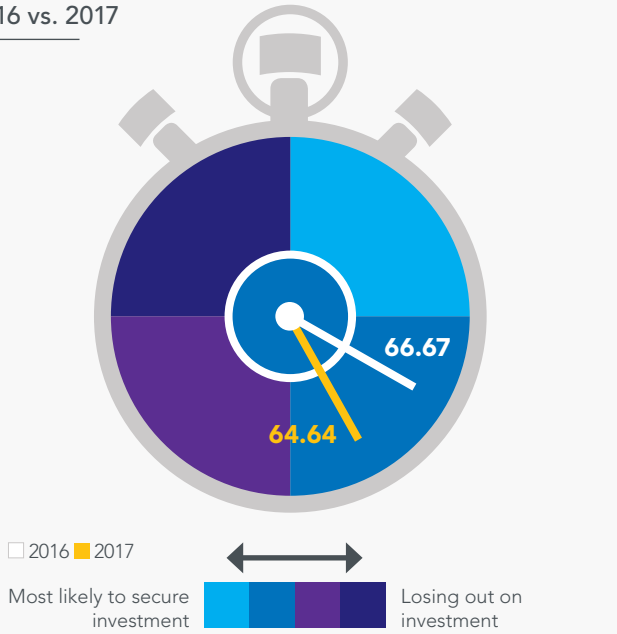
UAE

BCI Survey 2017 – Overall Scores

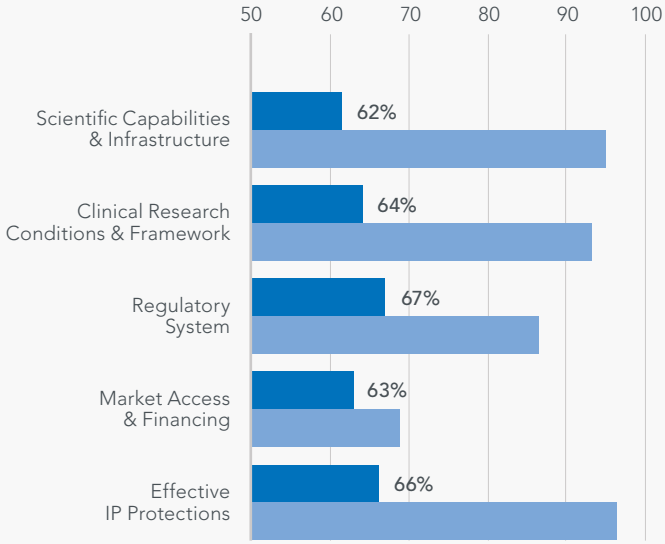
Comparison to Newcomer Markets



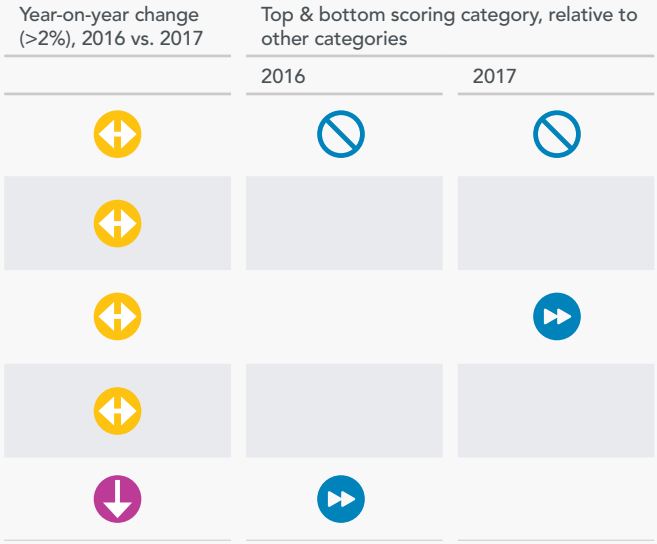
2016 vs. 2017



BCI Survey 2017 – Category Scores



UAE, % of total possible score
Top scorer, Newcomer Markets (Singapore), % of total possible score



Score rose
Score remained the same (<2% change in score)
Score fell
Top scoring category (LOW indicates a top scoring category <60% or where significant challenges remain)
Bottom scoring category

BCI Results In Depth: What helps and what hinders the UAE's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

✔ Though biopharmaceutical R&D capabilities continue to be viewed as at a fairly basic level, respondents regard the scientific education and training as becoming quite good.

✘ The extent of public-private partnerships is seen as limited, though the issue has been prioritized in the Vision 2021 and National Innovation Strategy.

Clinical Research Conditions & Framework

✔ A key strength is the CRO sector, which is seen as relatively advanced and with good compliance with global clinical research standards (GCP).

✘ Approval delays, together with some difficulties recruiting patients, are mentioned as ongoing stumbling blocks to clinical research.

The Regulatory System

✔ Compared to other newcomer markets timelines for new drug approval are rated as competitive, aided by the introduction of a fast track procedure in 2015.

✘ Drug review capacity is seen as mixed, especially for biologics and biosimilars.

Market Access & Financing

✘ A punitive system of price and profit controls is regarded as a major hindrance to increasing the country's attractiveness for biopharmaceutical investment.

✔ The reimbursement framework is regarded as quite comprehensive thanks to the role played by both public and private coverage schemes.

Effective Intellectual Property Protections

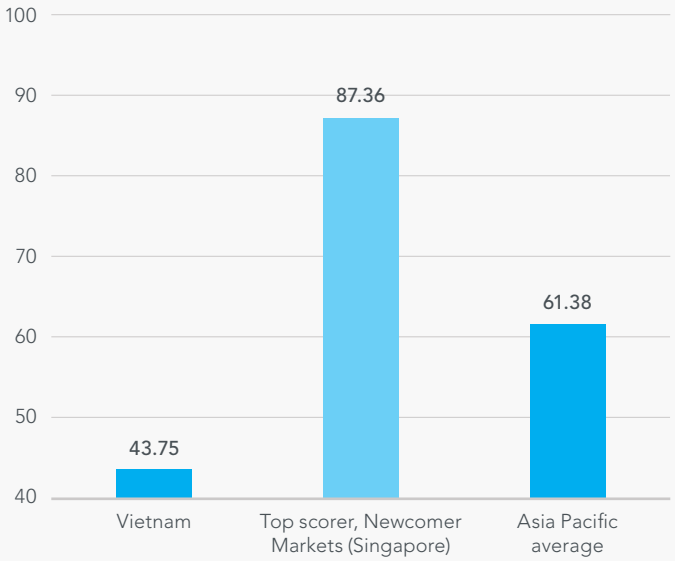
✘ Respondents register a worsening of the biopharmaceutical IP environment linked to recent instances of approving follow-on products that violate foreign patents, despite these being covered under its patent linkage mechanism.

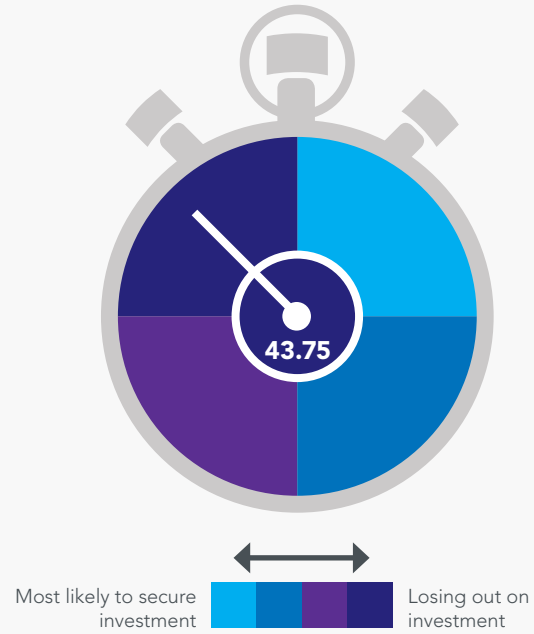
✔ A general framework for biopharmaceutical IP protection is regarded as being in place, though with important gaps such as RDP.

VIETNAM

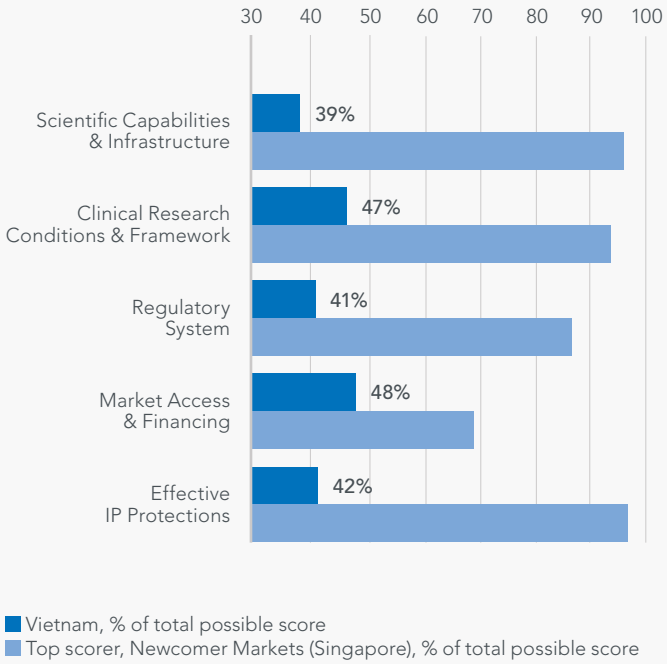
BCI Survey 2017 – Overall Scores

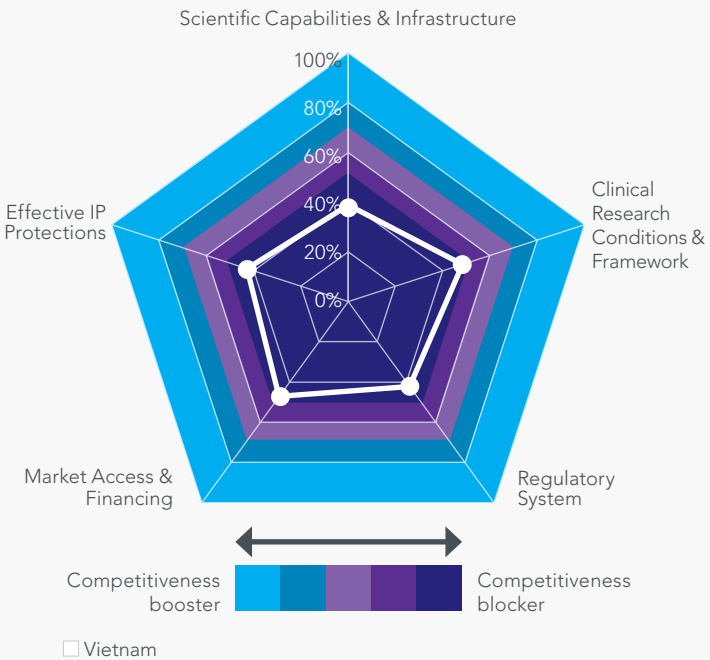
Comparison to Newcomer Markets





BCI Survey 2017 – Category Scores





BCI Results In Depth: What helps and what hinders Vietnam's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✘ The R&D system is perceived as challenging, with unpredictable conditions and excessive red tape cited as substantial roadblocks to investment in biopharmaceutical R&D.
- ✘ Collaborative development of medicines, particularly with public research institutions, is reportedly hampered by discriminatory treatment of foreign companies and corruption.

Clinical Research Conditions & Framework

- ✘ Although executives note low costs and a good level of patient interest in participation, overall clinical research conditions are seen as fairly weak.
- ✘ Respondents cite limited capacity and inadequate compliance with global clinical research standards among hospitals, health care providers and local CROs, as well as long delays in obtaining trial approval, as key deterrents.

The Regulatory System

- ✘ Drug review capacity and processes are seen as under-developed and highly opaque, leading to severe delays in drug approvals.
- ✘ Though efforts to improve are underway, certain standards for approval and quality control are seen as out of sync with international best practices (such as bioequivalence requirements for generics, biosimilar approval standards, and level of compliance with GMP) and substantially limit executives' confidence in the market.

Market Access & Financing

- ✘ What are seen as stringent and discriminatory price controls on imported products stifle competitiveness, as does uncertainty over the future of special (albeit limited) tenders for innovative medicines.
- ✘ Though Vietnam is seeking to progress towards universal health coverage, what is seen as lack of transparency in budgetary planning and inadequate means of access to non-reimbursed treatments through alternative/private channels limit the scope of reimbursement.

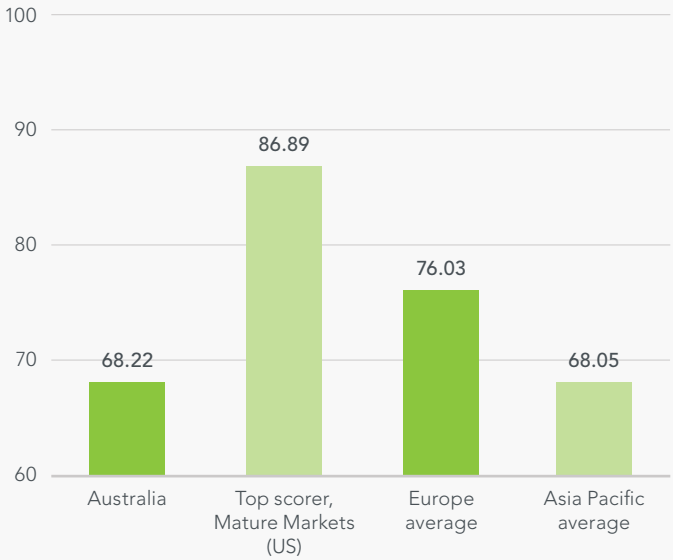
Effective Intellectual Property Protections

- ✘ Vietnam's biopharmaceutical IP regime is seen as a key factor hampering appetite for investment.
- ✘ The main gaps noted include narrow patenting criteria, a persistent and rising threat of compulsory licensing, weak enforcement of IP rights and lack of RDP in practice.

AUSTRALIA

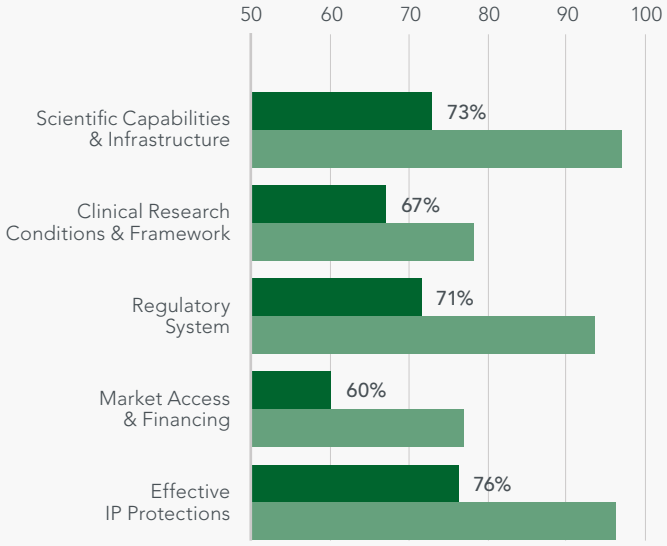
BCI Survey 2017 – Overall Scores

Comparison to Mature Markets



2016 vs. 2017

BCI Survey 2017 – Category Scores



Australia, % of total possible score
Top scorer, Mature Markets (US), % of total possible score

Year-on-year change (>2%), 2016 vs. 2017	Top & bottom scoring category, relative to other categories	
	2016	2017
↑		SLOW
↑	⊘	
↑		
↓	⊘	⊘
↔	SLOW	SLOW

Score rose · Score remained the same (<2% change in score) · Score fell

Top scoring category (SLOW indicates a top scoring category <60% or where significant challenges remain) ⊘ Bottom scoring category

BCI Results In Depth: What helps and what hinders Australia's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

✔ Respondents regard the science and R&D base as well developed.

✘ However, executives point to the need for a more systematic and coordinated collaboration between public authorities, industry, academia and the clinical community.

Clinical Research Conditions & Framework

✔ The level of preparedness and infrastructure for clinical trials is cited as top-notch and advancing, though mainly concentrated in capital cities.

✘ Financial costs and approval delays due to a fragmented ethics approval process are regarded as drawbacks of the clinical research environment.

The Regulatory System

✔ Executives cite slightly greater confidence in what is already considered good capacity for regulatory approval of biopharmaceuticals.

✘ Approval delays for innovative drugs are mentioned as a key challenge, though optimism exists towards a fast-track pathway currently being introduced.

Market Access & Financing

✘ Increasingly punitive price cuts and cost-containment measures are viewed as a topmost damper on investment attractiveness.

✘ Difficultly achieving reimbursement listing, coupled with very limited availability of alternative reimbursement channels, also reduces Australia's competiveness.

Effective Intellectual Property Protections

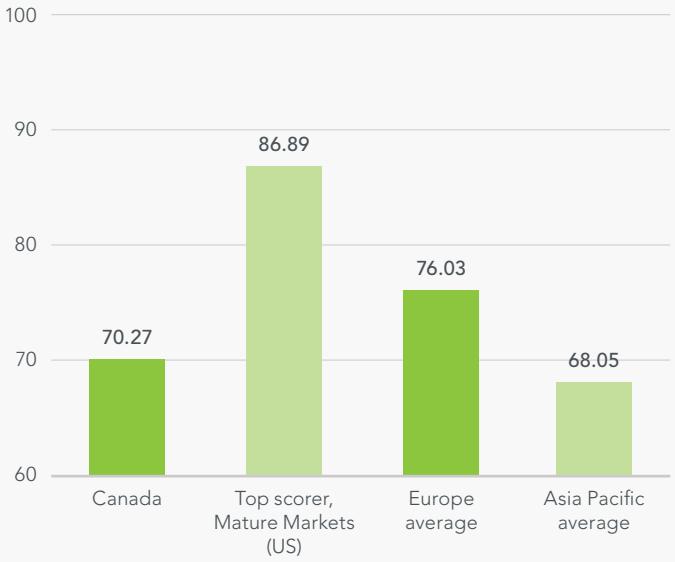
✘ Australia's IP environment is seen as seriously undermined by costs and uncertainty imposed by the lack of a notification system for potential patent infringement and the practice of seeking market-size damages from innovators that pursue unsuccessful patent claims.

✔ Ability to secure patent protection for biopharmaceutical inventions is regarded as generally satisfactory, though recent proposals from the Productivity Commission could risk changing this by raising the patentability threshold.

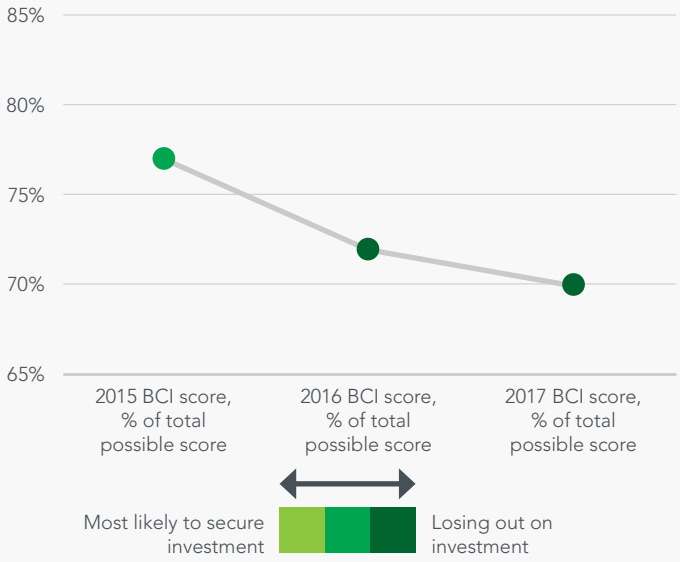
CANADA

BCI Survey 2017 – Overall Scores

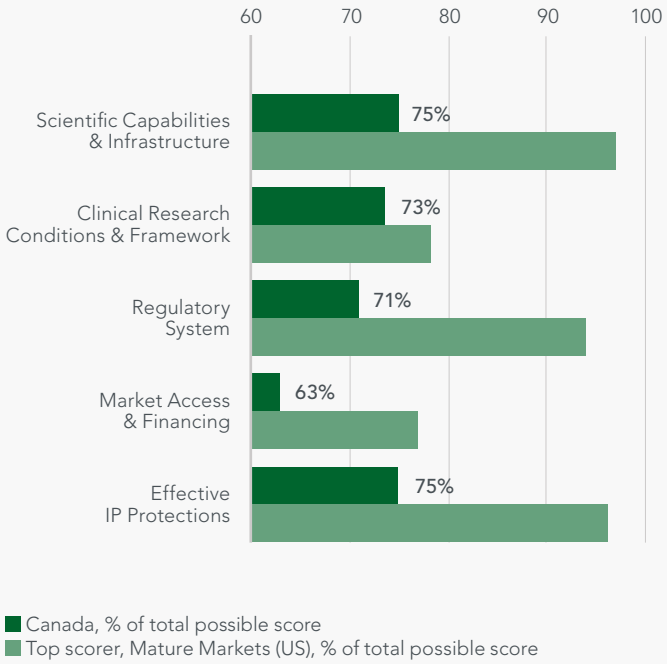
Comparison to Mature Markets

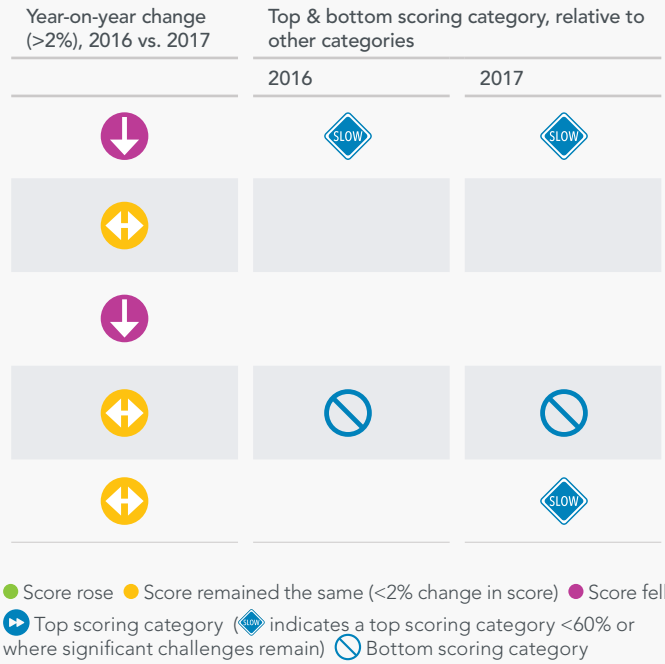


2015-2017



BCI Survey 2017 – Category Scores





BCI Results In Depth: What helps and what hinders Canada's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

✔ Executives cite an overall supportive science base for biopharmaceutical R&D, with relatively strong focus on cutting edge areas of R&D.

✘ Academia-industry collaboration is seen as occurring but not growing at full potential.

Clinical Research Conditions & Framework

✔ Streamlined clinical procedures and strong research capacity are cited as key strengths of the clinical research environment.

✘ However, executives note that financial costs of conducting clinical research in Canada are one factor holding it back in this area.

The Regulatory System

✔ The quality of drug review and approval is seen as fairly high.

✘ However, in the eyes of executives relatively less focus on supporting speedy review of innovative products is causing Canada to lose some ground compared to other mature markets.

Market Access & Financing

✘ Price controls on innovative biopharmaceuticals are perceived as one of the main barriers to investment, set to deteriorate more under proposed amendments to the Patented Medicine Regulations to further reduce the value placed on innovation in pricing decisions.

✘ Executives would welcome greater transparency in the pricing process.

Effective Intellectual Property Protections

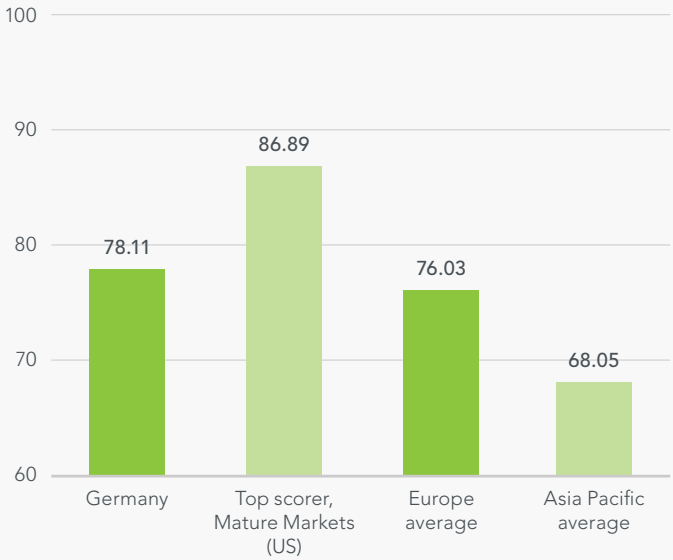
✔ Canada is viewed as having mixed biopharmaceutical IP conditions for innovation, though providing in executives' views a broadly supportive IP environment with a number of standard elements in place. While announced after the survey was conducted, the recent Canadian Supreme Court decision striking down the "promise doctrine" further supports that view.

✘ Yet, uncertainty over patentability requirements, thecurrent lack of patent term extension (at the time of the survey), and weaknesses in Canada's patent enforcement mechanism particularly dampen Canada's attractiveness for executives compared to other mature markets (with Canada scoring the lowest among all mature markets in the IP category).

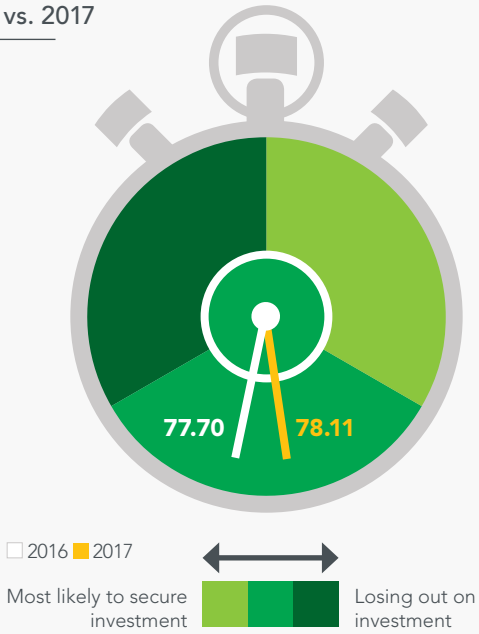
GERMANY

BCI Survey 2017 – Overall Scores

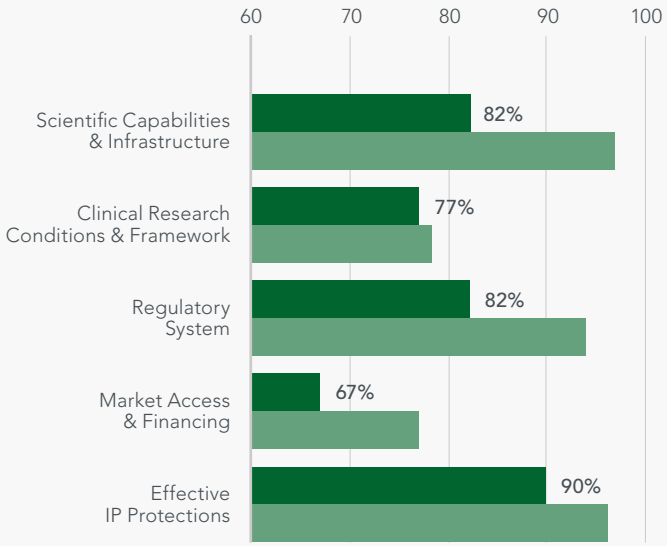
Comparison to Mature Markets



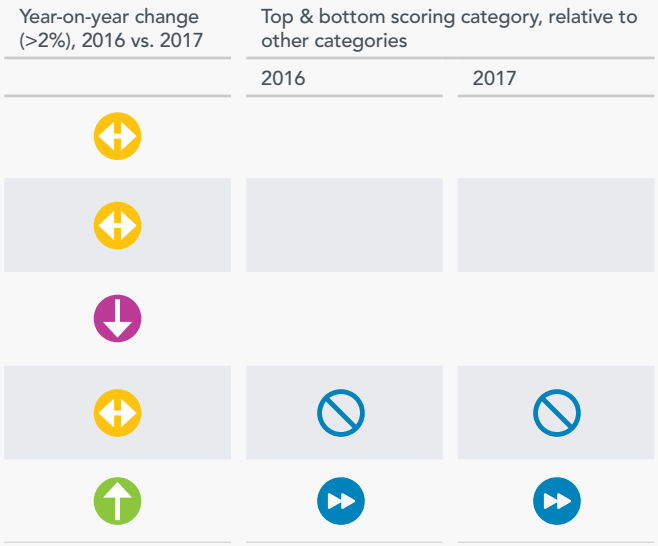
2016 vs. 2017



BCI Survey 2017 – Category Scores



Germany, % of total possible score
Top scorer, Mature Markets (US), % of total possible score



Score rose
Score remained the same (<2% change in score)
Score fell
Top scoring category (LOW indicates a top scoring category <60% or where significant challenges remain)
Bottom scoring category

BCI Results In Depth: What helps and what hinders Germany's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

✔ The science base and research infrastructure are considered to be of high quality, building on the presence of top-ranking universities and sustained R&D investment.

✔ Academic-industry collaboration continues to occur frequently with positive outcomes.

Clinical Research Conditions & Framework

✔ Executives cite expertise across all phases of clinical research as a factor supporting investment.

✘ Conducting trials in Germany is still viewed as being relatively costly compared to other mature markets.

The Regulatory System

✔ The regulatory framework and capacity for review is seen as being of a very high quality.

✘ What are considered to be relatively long approval timelines for medicines (mainly for national approval) and some lack of a good fast-track option at the national level are seen as slightly more troublesome in 2017.

Market Access & Financing

✘ One of the key drawbacks to biopharmaceutical investment in Germany remains what are seen as stringent price controls on innovative medicines.

✘ Tax conditions are generally considered by executives as less attractive compared to several other mature markets.

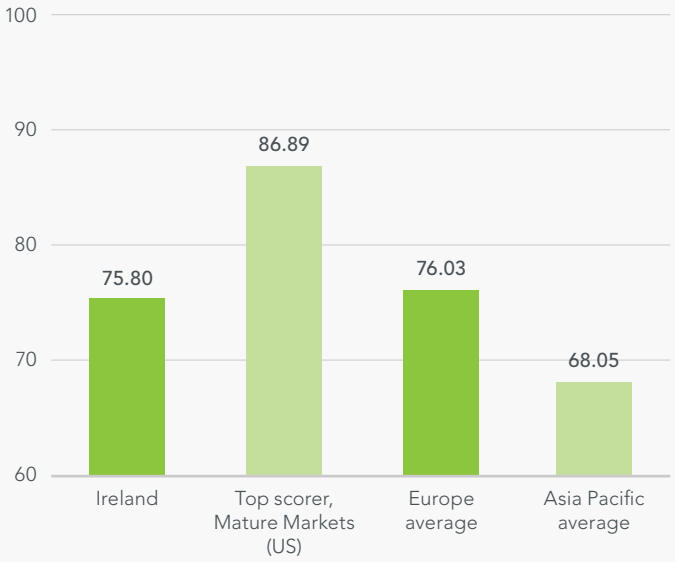
Effective Intellectual Property Protections

✔ Biopharmaceutical IP protection is viewed as being of the highest standards globally – and even more so by executives in 2017, though some uncertainty exists around ongoing reviews of biopharmaceutical IP-based incentives at the EU level.

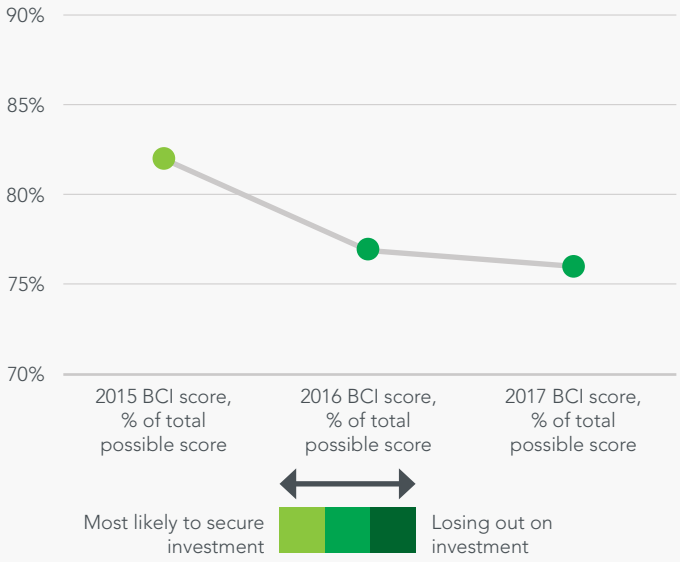
IRELAND

BCI Survey 2017 – Overall Scores

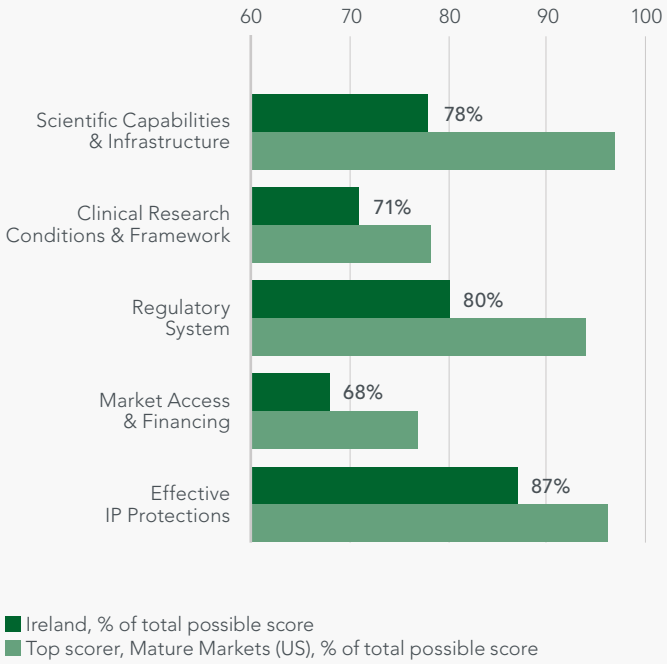
Comparison to Mature Markets

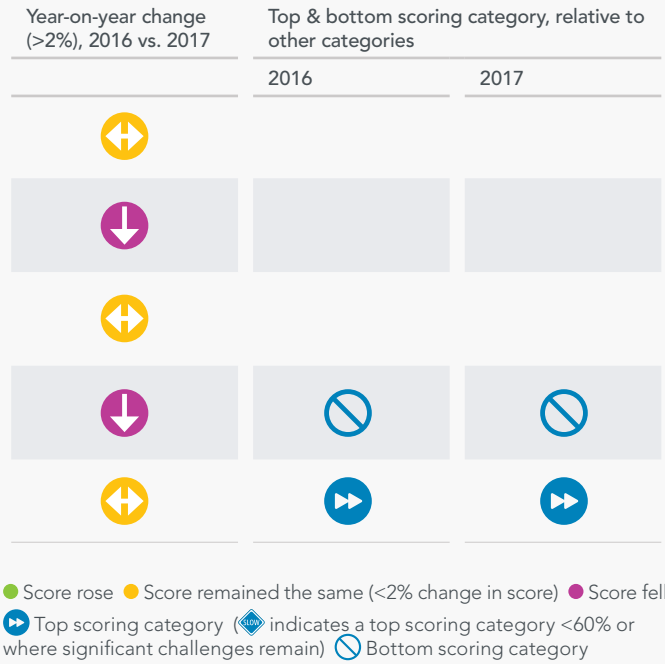


2015-2017



BCI Survey 2017 – Category Scores





BCI Results In Depth: What helps and what hinders Ireland's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ Biopharmaceutical R&D capabilities remain strong in local executives' perspective, with a solid knowledge base, R&D infrastructure, and funding available across the country.
- ✔ Translational R&D and academic-industry collaboration are viewed as progressing and increasingly focused on cutting edge R&D areas.

Clinical Research Conditions & Framework

- ✔ Capabilities for clinical research are considered to be at a satisfactory level including for complex and multi-centered trials across all disease types.
- ✘ Ireland is seen as losing some ground due to high costs and trial approval delays.

The Regulatory System

- ✔ Drug review and approval capacity is considered to be excellent.
- ✔ Approval timelines at both the EU and national levels are generally viewed as satisfactory, though fast-track pathways for priority innovative medicines could be improved.

Market Access & Financing

- ✘ The pricing & reimbursement environment is seen as Ireland's weakest link, particularly due to growing emphasis on cost containment and more rigid negotiating practices.
- ✔ Executives continue to rate what is seen as a supportive tax environment as an important driver of Ireland's investment attractiveness.

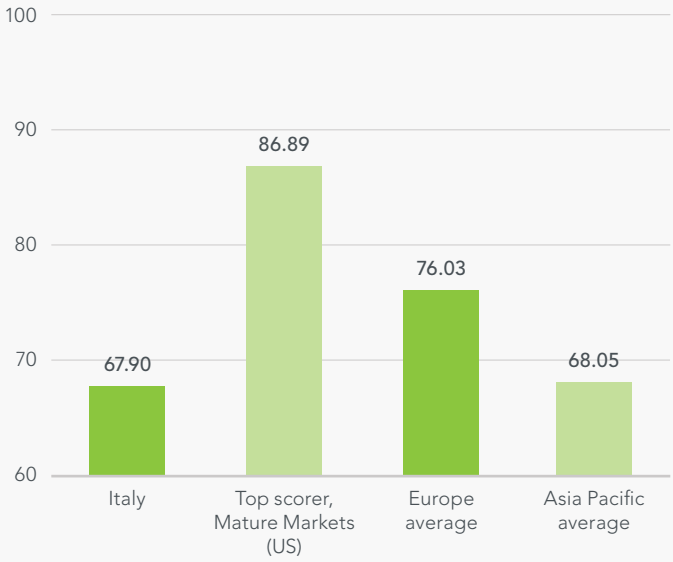
Effective Intellectual Property Protections

- ✔ The biopharmaceutical IP environment in Ireland and at the EU level is generally regarded as effective and strong (at the time the survey was conducted), though some uncertainty exists around ongoing reviews of biopharmaceutical IP-based incentives at the EU level.
- ✔ Executives are largely optimistic about the upcoming introduction of the European Unified Patent Court which is expected to further bolster the level of enforcement of IP rights.

ITALY

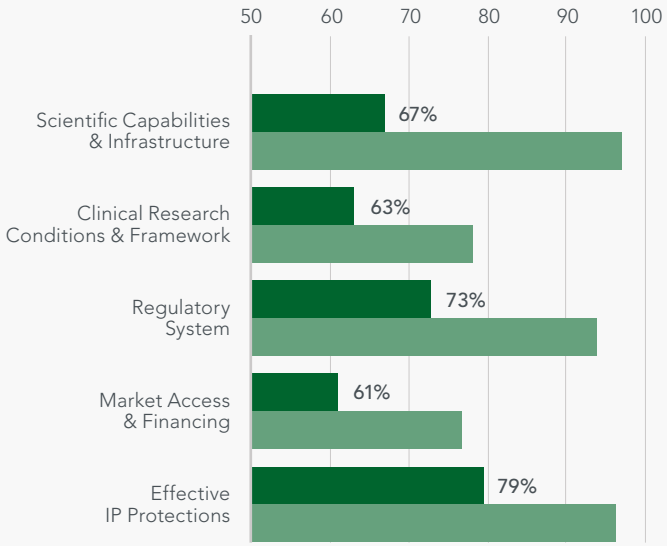
BCI Survey 2017 – Overall Scores

Comparison to Mature Markets



2016 vs. 2017

BCI Survey 2017 – Category Scores



Italy, % of total possible score
Top scorer, Mature Markets (US), % of total possible score

Year-on-year change (>2%), 2016 vs. 2017	Top & bottom scoring category, relative to other categories	
	2016	2017
↓		
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↔	⊘	⊘
↔	▶▶	▶▶

Score rose
Score remained the same (<2% change in score)
Score fell
Top scoring category (LOW indicates a top scoring category <60% or where significant challenges remain)
Bottom scoring category

BCI Results In Depth: What helps and what hinders Italy's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

✔ Executives mention availability of highly skilled researchers as one strength of the national scientific research environment.

✘ Research collaboration between public entities and industry in the field of biopharmaceuticals, particularly in new areas of R&D, continues to be regarded as an area for improvement.

Clinical Research Conditions & Framework

✔ Executives cite close ties between research centers and hospitals as distinct advantages, aiding in what is viewed as strong clinical research capabilities among hospitals.

✘ Bureaucratic hurdles and delays, especially in ethics committee review, are seen as significantly undermining competitiveness.

The Regulatory System

✔ Drug review capacity is viewed as fairly strong, and increasingly so in 2017.

✘ Executives raise regulatory delays at the national level as a disadvantage compared to other mature markets.

Market Access & Financing

✘ Executives raise concerns around regional authorities' involvement in pricing and reimbursement decisions, seen as slowing down reimbursement and creating inequalities in drug access across the country.

✘ Lack of alternative channels for accessing non-reimbursed drugs is seen as another impediment to the investment climate.

Effective Intellectual Property Protections

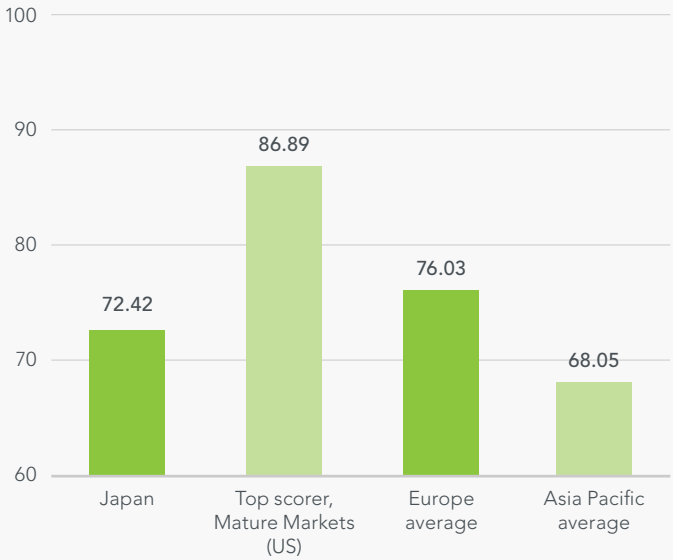
✔ The biopharmaceutical IP environment is viewed as a key enabler of innovation and investment in Italy.

✘ Some gaps exist in relation to remedies for infringement of IP rights in Italy. In addition, some uncertainty exists around ongoing reviews of biopharmaceutical IP-based incentives at the EU level.

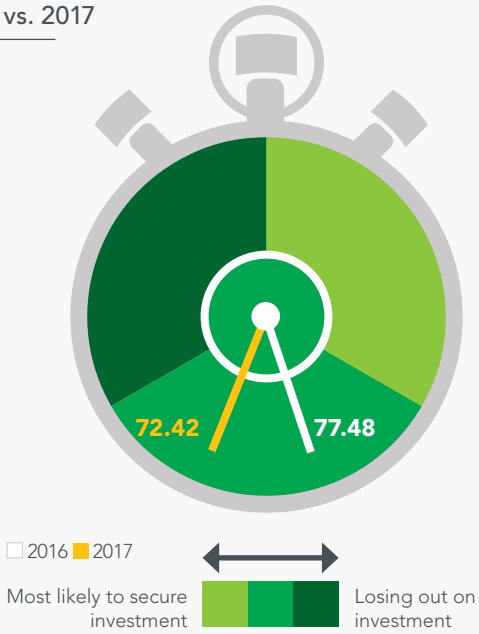
JAPAN

BCI Survey 2017 – Overall Scores

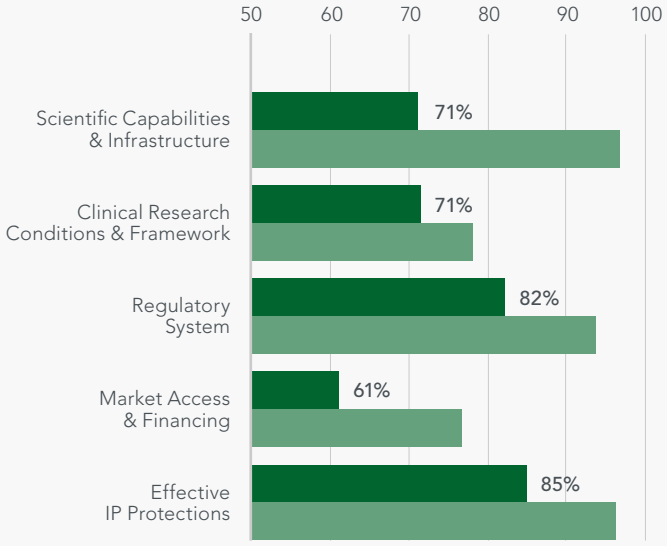
Comparison to Mature Markets



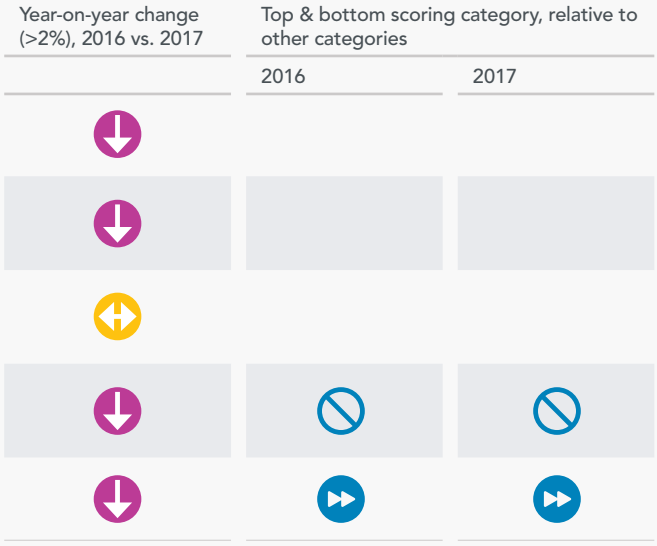
2016 vs. 2017



BCI Survey 2017 – Category Scores



Japan, % of total possible score
Top scorer, Mature Markets (US), % of total possible score



Score rose
Score remained the same (<2% change in score)
Score fell
Top scoring category (LOW indicates a top scoring category <60% or where significant challenges remain)
Bottom scoring category

BCI Results In Depth: What helps and what hinders Japan's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

✔ Respondents mention good drug development capabilities and government's support for pharmaceutical R&D as being of strategic importance for Japan.

✘ Compared to other advanced markets, the degree of cooperation between private and public research entities is increasingly viewed as behind the curve.

Clinical Research Conditions & Framework

✔ Executives see capacity for clinical research as adequate.

✘ High and rising costs and difficulty recruiting participants are regarded as hindering the competitiveness of the clinical research environment.

The Regulatory System

✔ The biopharmaceutical regulatory system is seen as strong and enforcing high standards.

✔ Executives mention shorter market approval timelines for innovative drugs, though room for further improvement exists.

Market Access & Financing

✘ Executives' confidence in the ability to secure an adequate price for breakthrough treatments is significantly lower in 2017 compared to 2016.

✘ Executives note that a greater focus on price controls and cost in the pricing and reimbursement system significantly hampers the investment climate.

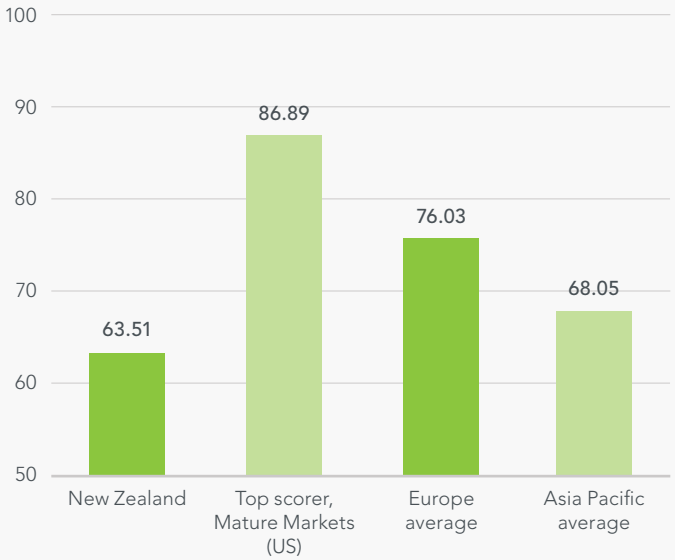
Effective Intellectual Property Protections

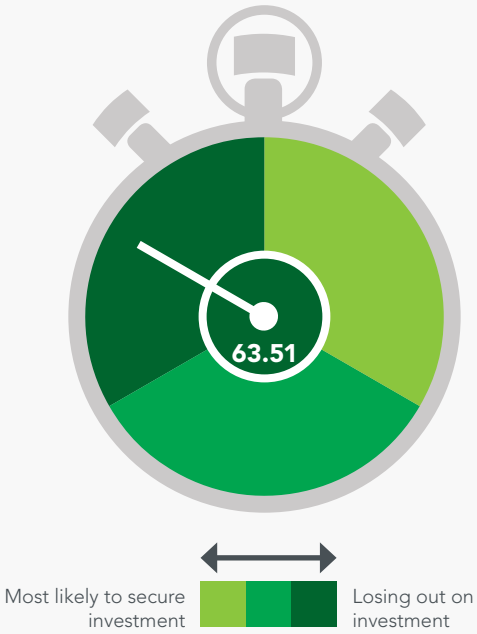
✔ Though confidence in government support for innovation colored executives' views of the IP environment slightly in 2017, overall Japan is seen as providing a robust level of biopharmaceutical IP protection.

NEW ZEALAND

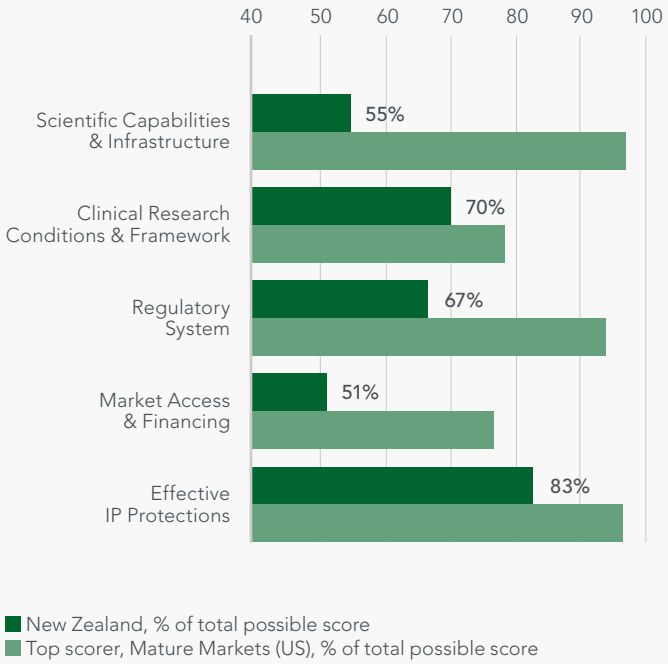
BCI Survey 2017 – Overall Scores

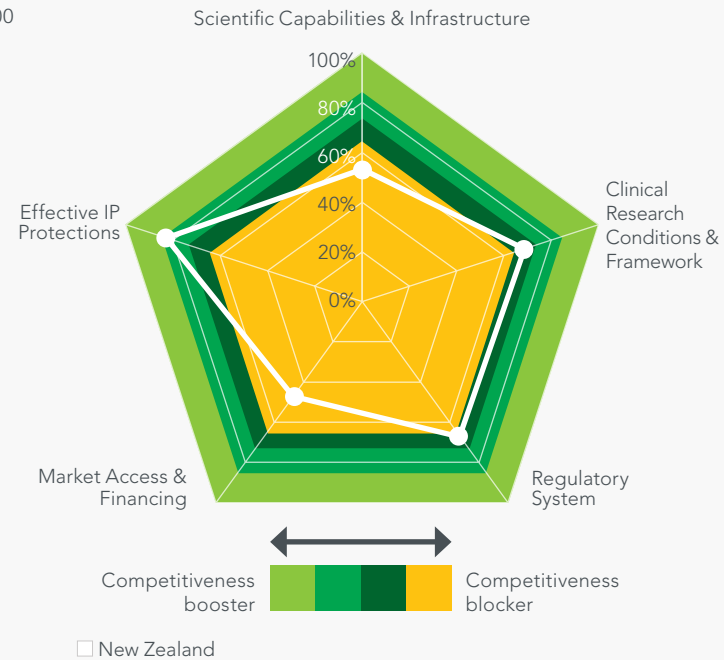
Comparison to Mature Markets





BCI Survey 2017 – Category Scores





BCI Results In Depth: What helps and what hinders New Zealand's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✘ Executives display a relatively low level of confidence in the biopharmaceutical R&D system.
- ✘ Collaboration between research institutions and industry is seen as limited and seriously undermined by an ongoing lack of government support for development and funding of innovative medicines.

Clinical Research Conditions & Framework

- ✔ Local executives cite relatively good capacity for conducting clinical research, though professional centers and clinical teams are viewed as under-funded.
- ✘ Some delays in trial approval exist, though are on par with those experienced in other mature markets.

The Regulatory System

- ✔ Drug approval capacity and frameworks are viewed as being of relatively high quality.
- ✘ Executives note difficulty introducing innovative treatments in a timely manner and current lack of fast-track pathways for priority treatments as impeding investment conditions.

Market Access & Financing

- ✘ The pricing and reimbursement environment in New Zealand is viewed as highly damaging to innovators and the central factor undermining investment.
- ✘ A capped budget for medicines that enjoys little growth (with no alternative channel for reimbursement), use of direct price cuts, and a narrow understanding of cost and savings are noted as particularly dissuading investment.

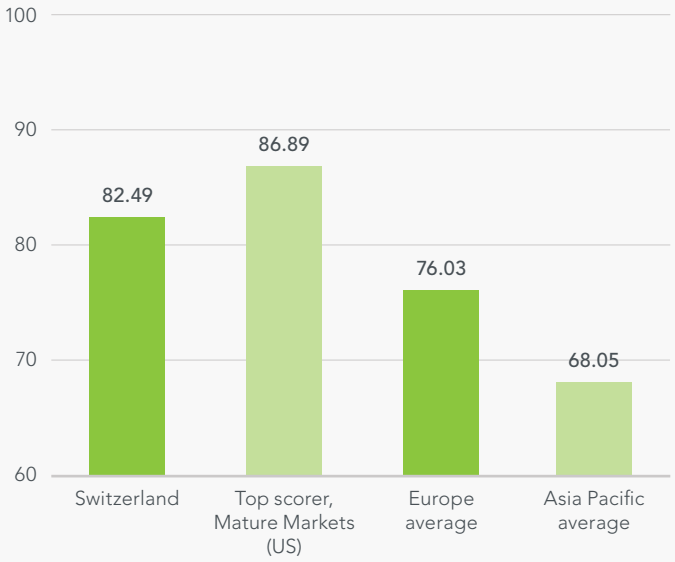
Effective Intellectual Property Protections

- ✔ New Zealand's biopharmaceutical IP protection regime is considered to be relatively strong and effective, though with some gaps.
- ✘ Executives cite the lack of patent term restoration and what is seen as inadequate RDP for biologics as additional challenges eroding New Zealand's competitiveness.

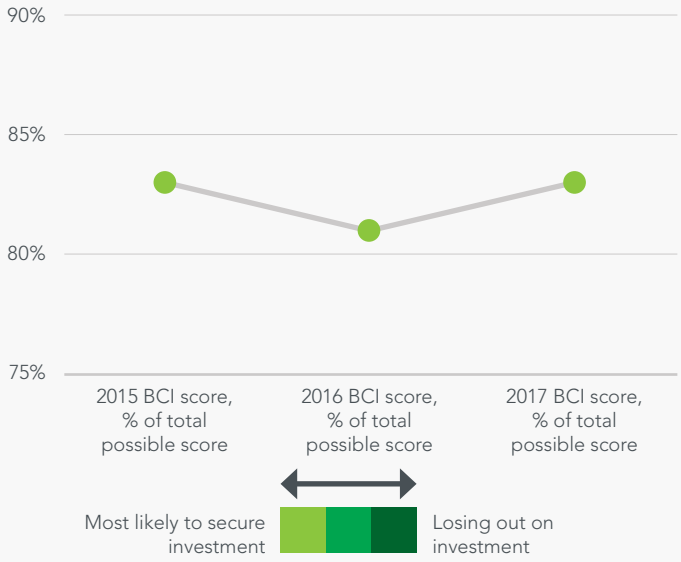
SWITZERLAND

BCI Survey 2017 – Overall Scores

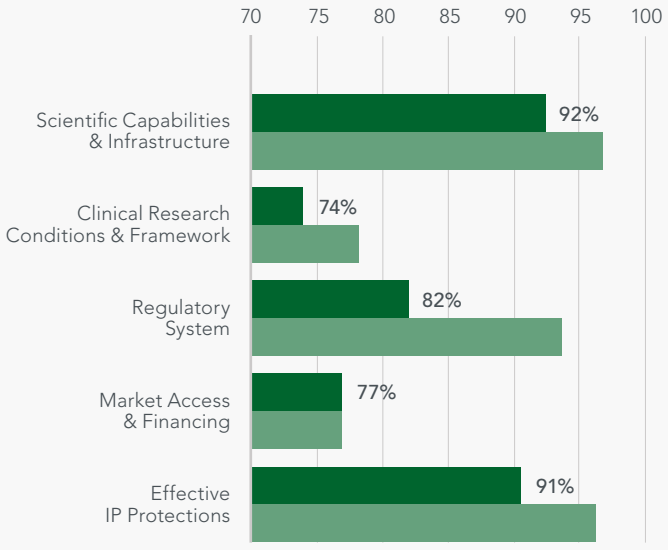
Comparison to Mature Markets



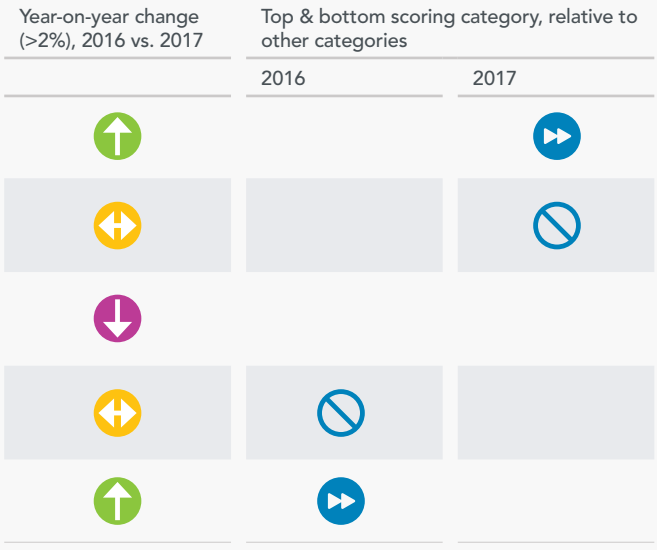
2015-2017



BCI Survey 2017 – Category Scores



Switzerland, % of total possible score
Top scorer, Mature Markets (US), % of total possible score



Score rose
Score remained the same (<2% change in score)
Score fell
Top scoring category (LOW indicates a top scoring category <60% or where significant challenges remain)
Bottom scoring category

BCI Results In Depth: What helps and what hinders Switzerland's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ Biopharmaceutical R&D capacities and infrastructure are regarded as first class, with renewed government support pledged under the most recent Federal Education, Research and Innovation Strategy.
- ✔ Areas of unmet need such as personalized health are increasingly prioritized in research activities (for instance, the 2017-2020 strategy of the Swiss Federal Institutes of Technology Domain), though still not seen as as occurring at the level of the US.

Clinical Research Conditions & Framework

- ✔ Scientific and regulatory capacity for clinical trials is regarded as quite strong.
- ✘ However, the cost of conducting clinical trials relative to other mature markets is a heavy factor weighing against investment.

The Regulatory System

- ✔ Local executives cite compliance with the highest standards by the drug regulator.
- ✘ Respondents mention relatively long approval timelines as an area for improvement.

Market Access & Financing

- ✘ Though executives indicate that adequate prices for innovative drugs are available in some instances, overall price controls are perceived as relatively stringent.
- ✔ Respondents mention a relatively wide scope of reimbursement, access to public tenders and tax conditions as key enablers of competiveness.

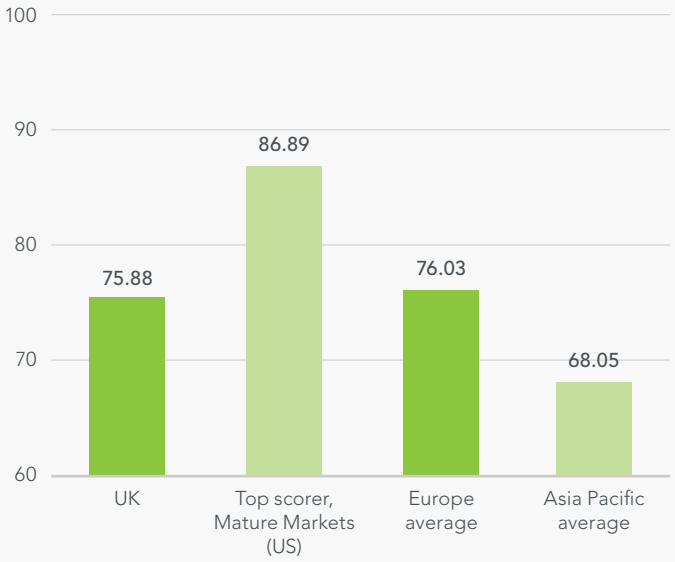
Effective Intellectual Property Protections

- ✔ The biopharmaceutical IP environment continues to be viewed as highly sophisticated and robust – even more so in 2017, though some uncertainty exists around ongoing reviews of biopharmaceutical IP-based incentives at the EU level.

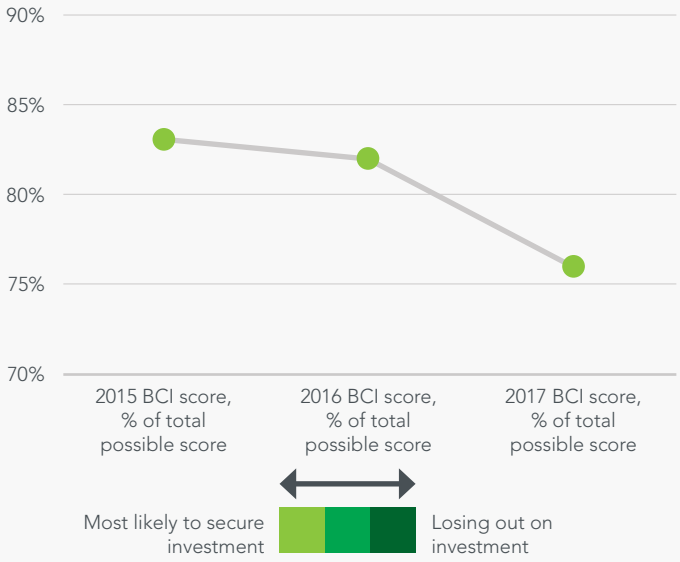
UK

BCI Survey 2017 – Overall Scores

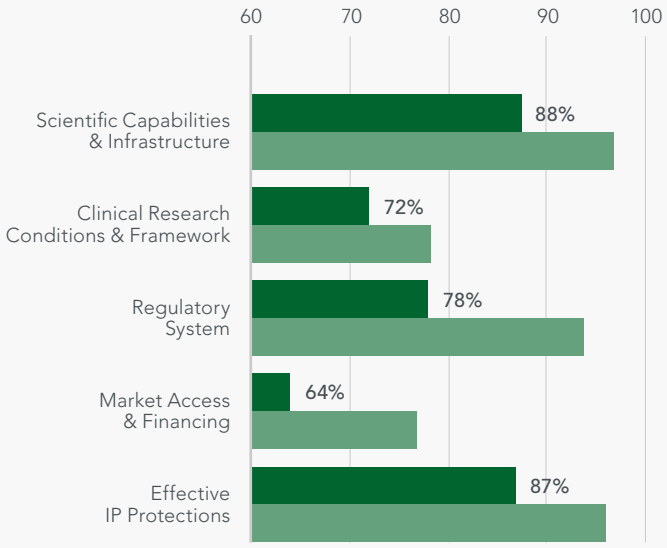
Comparison to Mature Markets



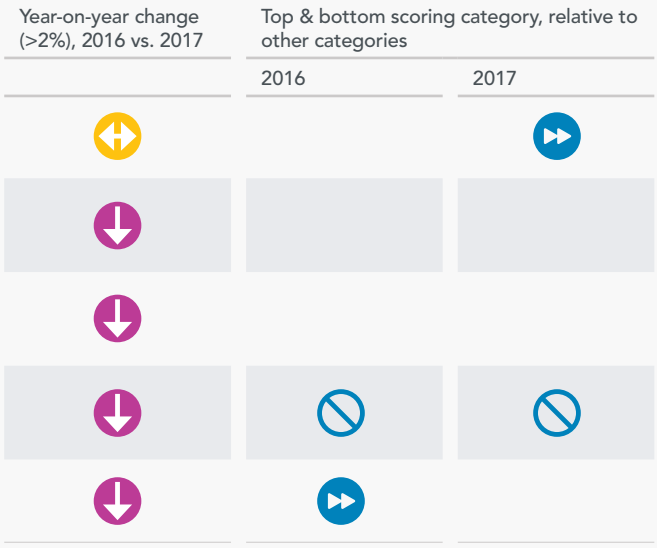
2015-2017



BCI Survey 2017 – Category Scores



UK, % of total possible score
Top scorer, Mature Markets (US), % of total possible score



Score rose
Score remained the same (<2% change in score)
Score fell
Top scoring category (LOW indicates a top scoring category <60% or where significant challenges remain)
Bottom scoring category

BCI Results In Depth: What helps and what hinders the UK's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ Biopharmaceutical R&D capabilities are considered to be of high quality, with strong emphasis on exploring treatments for breakthrough therapies and unmet clinical needs, though executives note that greater resources should be devoted to development of specialized skills in order to put the UK at the top globally.
- ✔ Executives note a good level of collaborative R&D within the life sciences, with strong government support.

Clinical Research Conditions & Framework

- ✔ Clinical research capabilities and conditions are generally viewed as strong, though inadequate incentives for participation by trusts and clinicians and rising costs of conducting trials weigh down competitiveness somewhat.
- ✘ Another growing drawback raised by executives is the lack of reimbursement of drugs used as comparators or in combination with the tested medicine, seen as an effect of cost containment measures.

The Regulatory System

- ✔ A high level of confidence exists in MHRA for review of biopharmaceuticals.
- ✘ Some uncertainty exists around implications of Brexit in terms of potential regulatory delays and cost implications for companies of a separate approval by MHRA.

Market Access & Financing

- ✘ Respondents note that a heavy and increasing focus on cost containment, including via rigid spending caps, price cuts, and limits to reimbursement, without an in-kind increase in drug uptake is seriously downgrading the UK's investment climate compared to other European markets.
- ✘ Tax incentives for innovators are viewed as attractive in certain areas but in other areas, such as the R&D tax credit, not as competitive as some of the UK's peers.

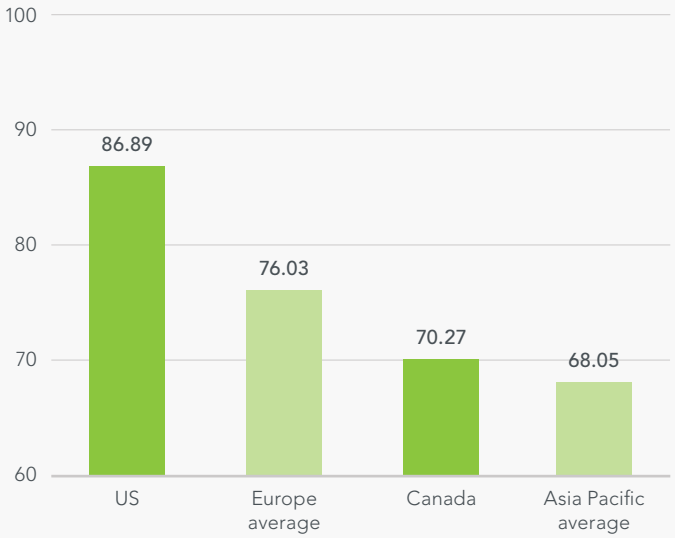
Effective Intellectual Property Protections

- ✔ The biopharmaceutical IP regime is regarded as strong and sophisticated, though some uncertainty as to the implications of Brexit for EU-related IP frameworks.

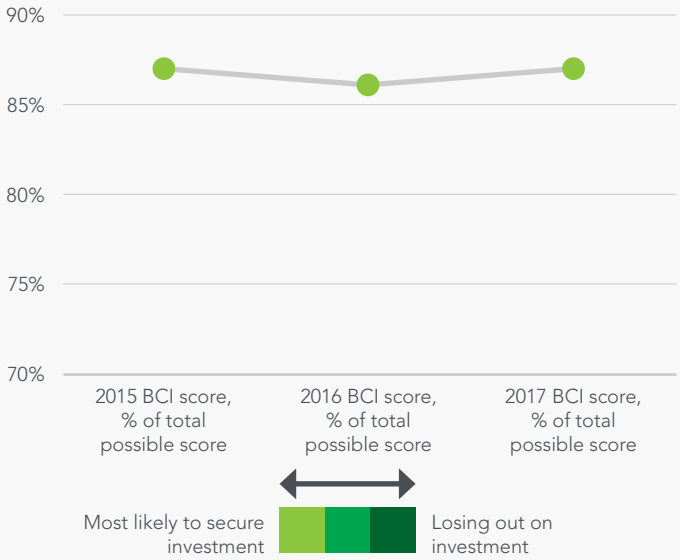
US

BCI Survey 2017 – Overall Scores

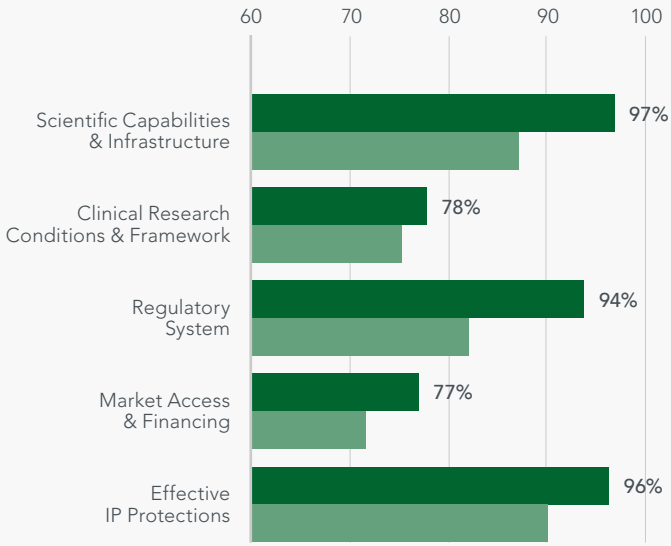
Comparison to Mature Markets



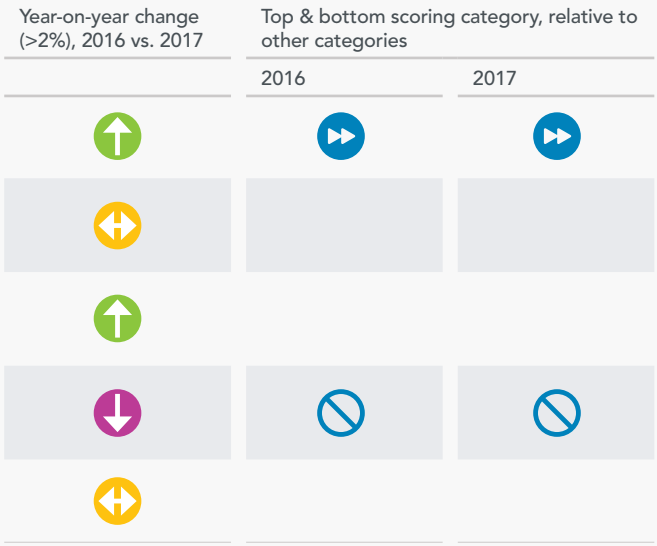
2015-2017



BCI Survey 2017 – Category Scores



US, % of total possible score
Average of Top 3 Mature Markets (excluding the US), % of total possible score



Score rose · Score remained the same (<2% change in score) · Score fell
Top scoring category (LOW indicates a top scoring category <60% or where significant challenges remain) · Bottom scoring category

BCI Results In Depth: What helps and what hinders the US's biopharmaceutical competitiveness?

Scientific Capabilities & Infrastructure

- ✔ The level of scientific education and biopharmaceutical R&D capabilities are seen as world class.
- ✔ Collaborative R&D and supportive technology transfer frameworks are also viewed as ongoing drivers of the US' thus far unrivaled competitiveness in the life sciences.

Clinical Research Conditions & Framework

- ✔ Executives cite a high level of expertise in clinical research.
- ✘ Cost of conducting trials relative to other markets is one detractor from selecting the US for clinical trials.

The Regulatory System

- ✔ The regulatory framework for biopharmaceuticals is by and large highly respected and seen as a benchmark globally, with some key exceptions (such as in the area of biosimilars).
- ✘ Regulatory delays are noted by executives, though are viewed as much shorter compared to other markets.

Market Access & Financing

- ✘ Though the market access environment is still seen as one of the most (if not the most) competitive worldwide, growing uncertainty around discussed introduction of government price controls (whether direct or indirect) risks costing the US its top spot in biopharmaceutical innovation.
- ✘ Tax conditions are viewed as sub-optimal, particularly in regard to the corporate income tax.

Effective Intellectual Property Protections

- ✔ Biopharmaceutical IP protection is viewed overall as being very strong.
- ✘ Some backtracking with regard to ability to patent certain types of biopharmaceuticals and a convoluted patent opposition system has undermined the US' attractiveness somewhat.

NOTES

1 OECDStat, "Gross domestic spending on R&D, total, % of GDP", accessed 2017

2 R&D Magazine, *Global R&D Funding Forecast*, Winter 2017, p.15

3 Genetic Engineering & Biotechnology News (GEN), "Top Eight Asia Biopharma Clusters 2016", 5/30/2016, www.genengnews.com/the-lists/top-eight-asia-biopharma-clusters-2016/77900669; Jones Lang LaSalle (2014), Life Sciences Cluster Report; GEN (2016), "Top 10 Non-US Hotspots for Biotech", 11/21/2016, www.genengnews.com/the-lists/top-10-non-us-hotspots-for-biotech-jobs/77900778

4 Moorkens, E. et al (2017), "The market of biopharmaceutical medicines: A snapshot of a diverse industrial landscape", *Frontiers in Pharmacology*, Vol.8, p.314; WSJ (2017), "Your cancer drugs may soon be discovered in China", 4/11/2017

5 See, for instance, the discussion and endnotes cited in section 2.1 of this report.

6 See, for instance: Pugatch Consilium (2017), *Building the Bioeconomy 2017: Examining National Biotechnology Industry Development Strategies Globally*, pp.21-25; Pugatch Consilium (2016), *Building the Bioeconomy 2016 Annex: Enabling Factors and Economy Case Studies*

7 GIPC (2017), The Roots of Innovation, US Chamber International IP Index, Fifth Edition, February 2016

8 See, for example: World Economic Forum (2016), *The Global Competitiveness Report 2016-2017*, Geneva; Cornell University, INSEAD, and WIPO (2015), *The Global Innovation Index 2017: Innovation Feeding the World*, Fontainebleau, Ithaca, and Geneva; World Bank (2016), *Doing Business 2017: Equal Opportunity for All*, Washington DC: World Bank; Scientific American Worldview Scorecard (2016); and GIPC (2017)

9 OECD (2006), p.171; Léger, A. (2006), "Intellectual Property Rights and Innovation in Developing Countries: Evidence from Panel Data", Proceedings of the German Development Economics Conference, Berlin

10 Chu, R. & Pugatch, M. (2010), *From Test Tube to Patient: National Innovation Strategies for the Biomedical Field*, Stockholm Network, p.17

11 Loscalzo, J. (2006), "The NIH Budget and the Future of Biomedical Research", *New England Journal of Medicine*; 354, pp.1665-1667

12 US FDA, "Basic Questions and Answers about Clinical Trials", www.fda.gov/forconsumers/byaudience/forpatientadvocates/hivandaidsactivities/ucm121345.htm; European and Developing Countries Clinical Trials Partnership (EDCTP) (2010) 2011 roadmap. p.2, http://ec.europa.eu/governance/impact/planned_ia/docs/2010_rtd_016_renewal_edctp_en.pdf; Allen Consulting Group (2006), Drivers of Pharmaceutical Industry Investment: Understanding Australia's Competitive Position. Final Report to Medicines Australia and Research Australia.

13 Pugatch Consilium (2014); Chu & Pugatch (2010)

14 Huang, S. (2012), "How can innovation create the future in a catching-up economy?: Focusing on China's pharmaceutical industry", *Journal of Knowledge-based Innovation in China*, Vol.4, Iss.2, pp.118-131; Nyasse, B. (2012), "Overview of Current Drug Discovery Activities in Africa and Their Links to International Efforts to Combat Tropical Infectious Diseases", *Drug Discovery in Africa*, pp.1-28

15 D Torstensson & M Pugatch (2010), *Keeping Medicines Safe – A Study of the Regulations Guiding the Approval of Medicines in Emerging Markets*, Stockholm Network London

16 WHO website, "GMP Questions and Answers", 2013, www.who.int/medicines/areas/quality_safety/quality_assurance/gmp/en/index.html

17 See, for instance: FDA, *Guidance for Industry Bioavailability and Bioequivalence Studies for Orally Administered Drug Products – General Considerations*, March 2003; FDA, *Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009 Guidance for Industry*, April 2015

18 *The Economist* (2014), "Fever rising", February 15 2014

19 M. Kyle (2007), "Pharmaceutical price controls and entry strategies", *Review of Economics and Statistics*, Vol. 89, No. 1, February 2007, pp. 88-99

20 Cavazos, R. et al, (2010), *Policy Complements to the Strengthening of IPRS in Developing Countries*, OECD Trade Policy Working Papers, No. 104, OECD Publishing.

21 A. Kesselheim, (2010), "Using Market-Exclusivity Incentives to Promote Pharmaceutical Innovation", *New England Journal of Medicine*, Vol.363, No.19 pp.1855-1862

22 OECDStat, "Gross domestic spending on R&D, total, % of GDP", accessed 2017

APPENDIX: 2017 BCI SURVEY TEXT

NEWCOMER MARKETS BCI SURVEY

SCIENTIFIC CAPABILITIES & INFRASTRUCTURE

Question 1
How would you describe the overall level of your country in terms of its capabilities to engage in biopharmaceutical research and development?

Low (seriously behind other countries) ☐	Basic ☐	Significant (more than other countries, but still lacking in some areas) ☐	Excellent (top of the curve) ☐

Question 2
In your view, the level of scientific education and training in your country is:

Low (very basic and incomplete knowledge base) ☐	Basic (not sufficiently advanced to meet modern developments) ☐	Significant (more than other countries, but still lacking in some areas) ☐	Excellent (of the highest caliber across the board) ☐

Question 3
How strong and effective is the level of collaboration in your country between research institutions and the biopharmaceutical industry?

Almost no collaboration ☐	Occurs occasionally ☐	Occurs frequently ☐	Occurs daily (is of a strategic interest) ☐

CLINICAL RESEARCH CONDITIONS AND FRAMEWORK

Question 4
How would you describe the readiness and capabilities of hospitals in your country to carry out clinical trials of different phases?

Low (limited capacity for conducting clinical trials) ☐	Basic (focusing mostly on post-clinical phases) ☐	High (strong capabilities for conducting clinical trials of different phases, but mostly final phase trials, i.e. phase III, are taking place) ☐	Excellent (of the highest caliber across the board; hospitals conduct and lead clinical trials in all phases and their standards are harmonized with global GCP standards) ☐

Question 5
How easy is it to recruit and maintain volunteers for participating in clinical trials in your country?

Very difficult (greatly lacking in volunteers; adverse public perception) ☐	Relatively difficult (volunteers are available but in insufficient numbers; officials anxious about public perception) ☐	Relatively easy (some limitations in the ability to secure long-term participation; public perception generally positive or not a factor) ☐	Easy (high level of success in recruiting and maintaining candidates; positive public perception) ☐

Question 6
Compared to newcomer markets, how costly is it to conduct clinical trials in your country?

Financially unattractive (facilities and manpower are relatively expensive and difficult to access) ☐	Relatively costly ☐	Relatively less costly ☐	Financially attractive (infrastructure and manpower of adequate quality are relatively inexpensive to secure) ☐

Question 7
In your view, what is the typical timeframe for obtaining approval for a clinical trial in your country?

More than 180 days or unpredictable ☐	90-180 days ☐	60-90 days ☐	30-60 days or less ☐

Question 8
How compliant are organizations participating in clinical trials in your country with global clinical standards (GCP) and procedures?

Compliance is lacking ☐	Compliance varies ☐	Relatively compliant (with exceptions) ☐	Very compliant (across the board) ☐

Question 9
How developed is the clinical research management (CRM) industry in your country?

Undeveloped ☐	Limited (in terms of presence and capacity) ☐	Fairly developed (with room for improvement) ☐	Highly developed (of the highest standard across the board) ☐

THE REGULATORY SYSTEM – DRUG APPROVAL, QUALITY ASSURANCE AND PHARMACOVIGILANCE

Question 10
How would you describe the capacity of the health regulator in your country to review the data submitted to it for the approval of new biopharmaceutical products?

Very low (low capacity for independent review) ☐	Basic (most reviews based on prior approval in other countries; lacks significant capacity for independent review) ☐	Good (review based on prior approval in other countries as well as on independent review) ☐	Excellent (full capacity to conduct independent review) ☐

Question 11
In your view, how long are delays in the registration of an innovative drug that has already been approved by a major drug agency in a mature market (such as the FDA or EMA)?

Very long (takes 24 months or more, despite having data from prior approval in other countries) ☐	Relatively long (takes 12 months or more) ☐	Fairy short (takes 6-12 months) ☐	Very short (takes no more than 6 months) ☐

Question 12
How would you describe the capacity of the health regulator in your country to review and approve generic drugs (based on small molecules/chemical entities)?

No capacity (approval is automatic or not necessary) ☐	Limited (only bioequivalence tests are required) ☐	Reasonable (quality, safety and efficacy data is also required, but gaps remain in terms of phasing out substandard drugs) ☐	Excellent (regulatory framework requires approval according to the highest acceptable scientific standards) ☐

Question 13
How would you describe the capacity of the health regulator in your country to review and approve biosimilars (based on large molecules/biologics)?

No capacity (approval is automatic or not necessary, or only requires bioequivalence tests) ☐	Limited (preclinical and/or clinical testing is required for approval but only a minimal amount) ☐	Reasonable (adequate preclinical and clinical testing is required and clearly defined in most cases) ☐	Fully satisfactory (regulatory framework fully in line with WHO principles of biosimilar approval and standards are clearly defined across the board) ☐

Question 14
In your view, to what extent are locally manufactured products in your country compliant with GMP rules that conform to international standards?

Compliance is lacking and/ or GMP rules are below international standards ☐	Compliance varies ☐	Relatively compliant (with exceptions) vis-à-vis international GMP standards ☐	Very compliant (across the board) and GMP rules are in line with international standards ☐

Question 15
How would you describe the pharmacovigilance system in your country?

Non-existent ☐	Basic (rudimentary reporting system, frequent delays, inadequate response) ☐	Relatively effective (adequate reporting system and response in most cases, with some exceptions) ☐	High-level (effective reporting system; rapid and comprehensive response) ☐

MARKET ACCESS AND FINANCING

Question 16
How comprehensive is the public reimbursement framework in your country?

Non-existent (there is no national or public reimbursement of pharmaceutical products) ☐	Partial (reimbursement is usually given to less costly and domestically manufactured products, i.e. focus is on generics) ☐	Relatively comprehensive (most medicines are reimbursed, but severe limitations are imposed on drugs which are considered relatively more costly) ☐	Fully comprehensive (reimbursement is given across the board, including the possibility of reimbursing costlier, innovative medicines) ☐

Question 17
How would you describe the transparency of the public pricing and reimbursement framework in your country?

Completely non-transparent (decisions take place behind fully closed doors; industry has little influence on or knowledge of the actual decision making process) ☐	Limited transparency (industry participates in negotiations but has only limited access to the basis of final pricing decisions) ☐	Quite transparent (industry routinely participates in decisions but is not privy to all aspects of the process) ☐	Fully transparent (rationale, data and personnel involved in decisions are entirely public information and are developed in collaboration with industry and key stakeholders, e.g. patients) ☐

Question 18

How stringent are price controls on publicly reimbursed products in your country?
*If biopharmaceutical products are not publicly reimbursed in your country please select the first option.

Highly stringent (prices are determined by the state and are highly restrictive) ☐	Relatively stringent (price controls are imposed but to a limited extent) ☐	Moderate (companies are allowed to set their own prices, subject to structural limitations, such as profit margins and negotiations) ☐	Relatively free pricing (there are almost no limitations on how prices are set at the national level) ☐

Question 19

In the absence of public reimbursement (or serious delays), to what extent are private or supplementary channels that allow patients to access biopharmaceutical products available in your country?

Not available (such channels do not exist in my country) ☐	Sporadically (mainly through out-of-pocket spending on individual drugs) ☐	Partially (supplementary coverage schemes are available, but mainly for certain income levels or disease areas) ☐	Frequently (the population can choose from various supplementary and commercial coverage schemes that allow access to a significant number of treatments) ☐

Question 20

To what extent does the public procurement system in your country allow your organization to effectively compete to provide patients access to your products?

Hardly at all (the process is heavily biased and/or providers/payers have all the negotiating power) ☐	To a limited extent (only in cases in which the product is very strong) ☐	To a reasonable extent (providers or other bid participants have an advantage some of the time) ☐	To a great extent (we are able to compete with other bids and/or negotiate with providers on an equal footing) ☐

EFFECTIVE IP PROTECTIONS

Question 21

How effective are the IP protections associated with proprietary pharmaceutical products in your country?

Non-existent (high risk environment in which products are immediately deprived of protection) ☐	Ineffective (both in terms of the length and the scope) ☐	Relatively effective (reasonable length, yet the scope of protection is frequently challenged and disputed) ☐	Highly effective (both in terms of the length and scope of protection) ☐

Question 22
How effective is the process of patenting in your country?

Highly ineffective (complex and slow, with a very poor degree of professional examination capacity) ☐	Somewhat ineffective (a bureaucratic process with a fairly low level of expertise in the examination process) ☐	Fairly effective (professional, but with some exceptions) ☐	Highly effective (in line with current international standards; streamlined process for both domestic and international patents) ☐

Question 23
How effective are mechanisms in your country aimed at safeguarding clinical trial data (i.e. regulatory data protection)?

Non-existent (no such framework exists) ☐	Little effectiveness (the framework is very limited both in relation to term of exclusivity and scope) ☐	Partially effective (a framework exists but is mainly applicable only to new chemical entities and does not cover biologic products) ☐	Very effective (the framework generally applies to all types of innovative medicines, including biologics and new indications) ☐

Question 24
In your view, how effective are civil and criminal remedies for infringement of intellectual property rights and battling counterfeit medicines in your country?

Highly ineffective (framework for litigation and penalties does not exist) ☐	Fairly ineffective (framework exists but is generally not implemented or enforced) ☐	Fairly effective (framework is generally implemented and enforced but with key exceptions) ☐	Very effective (including compensation, injunctions, seizures and penalties; ability to challenge validity of a patent) ☐

Question 25
To what extent does your country have in place a regulatory patent enforcement mechanism for biopharmaceuticals that allows for patent dispute resolution prior to the marketing of a potentially infringing product?

Non-existent (no patent linkage framework exists and judicial remedies are ineffective) ☐	On a limited basis (a partial mechanism is in place but is applied inconsistently or is restricted to certain types of patents ☐	To a reasonable extent (a formal mechanism is in place that effectively enables timely dispute resolution, with some exceptions) ☐	To a great extent (a strong mechanism is in place and allows for timely and effective biopharmaceutical patent enforcement across the board ☐

MATURE MARKETS BCI SURVEY

SCIENTIFIC CAPABILITIES & INFRASTRUCTURE

Question 1

How would you describe the overall level of your country in terms of its capabilities to engage in biopharmaceutical research and development?

Low (seriously behind other countries) ☐	Basic ☐	Significant (more than other countries, but still lacking in some areas) ☐	Excellent (top of the curve) ☐

Question 2

In your view, the level of scientific education and training in your country is:

Low (very basic and incomplete knowledge base) ☐	Basic (not sufficiently advanced to meet modern developments) ☐	Significant (more than other countries, but still lacking in some areas) ☐	Excellent (of the highest caliber across the board) ☐

Question 3

How strong and effective is the level of collaboration in your country between research institutions and the biopharmaceutical industry?

Almost no collaboration ☐	Occurs occasionally ☐	Occurs frequently ☐	Occurs daily (is of a strategic interest) ☐

Question 4

How would you rank the R&D capacity in your country in terms of exploring treatments for new areas and unmet needs, including localized needs, rare diseases and personalized medicine?

Low (R&D capabilities for new areas are lacking) ☐	Basic (despite certain areas of strength, capabilities have yet to be translated into concrete platforms) ☐	Significant (notable initiatives for R&D into new diseases areas and personalized treatments exist) ☐	Excellent (the capacity and application of R&D into new areas and tailored needs is at the top globally) ☐

CLINICAL RESEARCH CONDITIONS AND FRAMEWORK

Question 5
How would you describe the readiness and capabilities of hospitals in your country to carry out clinical trials of different phases?

Low (limited capacity for conducting clinical trials) ☐	Basic (focusing mostly on post-clinical phases) ☐	High (strong capabilities for conducting clinical trials of different phases, but mostly final phase trials, i.e. phase III, are taking place) ☐	Excellent (of the highest caliber across the board; hospitals conduct and lead clinical trials in all phases and their standards are harmonized with global GCP standards) ☐

Question 6
How easy is it to recruit and maintain volunteers for participating in clinical trials in your country?

Very difficult (greatly lacking in volunteers; adverse public perception) ☐	Relatively difficult (volunteers are available but in insufficient numbers; officials anxious about public perception) ☐	Relatively easy (some limitations in the ability to secure long-term participation; public perception generally positive or not a factor) ☐	Easy (high level of success in recruiting and maintaining candidates; positive public perception) ☐

Question 7
Compared to other mature markets, how costly is it to conduct clinical trials in your country?

Financially unattractive (facilities and manpower are relatively expensive and difficult to access) ☐	Relatively costly ☐	Relatively inexpensive ☐	Financially attractive (high quality infrastructure and manpower are relatively inexpensive to secure) ☐

Question 8
In your view, what is the typical timeframe for obtaining approval for a clinical trial in your country?

More than 180 days or unpredictable ☐	90-180 days ☐	60-90 days ☐	30-60 days or less ☐

THE REGULATORY SYSTEM

Question 9
How would you describe the capacity of the health regulator in your country to review the data submitted to it for the approval of new biopharmaceutical products?

Very low (low capacity for independent review) ☐	Basic (most reviews based on prior approval in other countries; lacks significant capacity for independent review) ☐	Good (review based on prior approval in other countries as well as on independent review) ☐	Excellent (full capacity to conduct independent review) ☐

Question 10
In your view, what is the timeframe for the health regulator in your country to examine and approve a drug once it has received all available data?

Very long (takes 24 months or more, even where data from prior approval in other countries is available) ☐	Relatively long (takes 12 months or more) ☐	Fairy short (takes 6-12 months) ☐	Very short (takes no more than 6 months) ☐

Question 11
To what extent do designated fast-track pathways for priority innovative biopharmaceutical products exist in your country?

None (such pathways do not exist at the moment) ☐	Basic (framework for a fast-track pathway(s) exist but are not actually operational or effective) ☐	Satisfactory (designated fast-track pathways are in place and are being used) ☐	Excellent (fast-track pathways are fully operational and produce concrete results in terms of the ability to introduce priority products to the market) ☐

Question 12
How would you describe the capacity of the health regulator in your country to review and approve biosimilars (based on large molecules/biologics)?

No capacity (approval is automatic or not necessary, or only requires bioequivalence tests) ☐	Limited (preclinical and/or clinical testing is required for approval but only a minimal amount) ☐	Reasonable (adequate preclinical and clinical testing is required and clearly defined in most cases) ☐	Fully satisfactory (regulatory framework fully in line with WHO principles of biosimilar approval and standards are clearly defined across the board) ☐

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Question 16
To what extent are innovators in your country able to secure an adequate price for breakthrough treatments that provide significant therapeutic value compared to existing treatments?

Rarely (payers are mostly focused on the price and cost of these medicines and not on their value) ☐	Partially (while acknowledging the therapeutic value of these products, the reimbursement framework does not fully reflect this value) ☐	Reasonably (most breakthrough treatments are reimbursed or financially supported in a manner that also takes into account their high value to the patient ☐	Fully (a real understanding of the need for reimbursing breakthrough products in a manner consistent with their long term contribution to patients and society, and is applied on the ground ☐

Question 17

In the absence of public reimbursement (or serious delays), to what extent are private or supplementary channels that allow patients to access biopharmaceutical products available in your country?

Not available (such channels do not exist in my country) ☐	Sporadically (mainly through out-of-pocket spending on individual drugs) ☐	Partially (supplementary coverage schemes are available, but mainly for certain income levels or disease areas) ☐	Frequently (the population can choose from various supplementary and commercial coverage schemes that allow access to a significant number of treatments) ☐

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Question 19

To what extent do alternative market entry agreements exist in your country for biopharmaceutical products that are not (fully) reimbursed through the relevant/dominant national, regional or private payer?

Non-existent (such agreements are not utilized) ☐	On a limited basis (such agreements are piloted or used for a small number of products) ☐	Partially (such agreements are being applied to and enabling market access for a growing number of strategic products) ☐	Regularly (such agreements are used frequently for strategic products and allow for effective market access) ☐

Question 20

In your view, how attractive is the tax environment for the biopharmaceutical industry in your country?

Highly unattractive (high corporate tax rate and no special tax-related incentives for businesses or R&D) ☐	Somewhat unattractive (neutral tax rate but few special incentives) ☐	Somewhat attractive (there are one or two major deterring factors relative to other markets, e.g. poor tax rate or lack of a certain incentive) ☐	Highly attractive (relatively low corporate tax rate and several different tax break schemes including for R&D and SMEs) ☐

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Question 24
In your view, how effective are administrative, civil and criminal remedies for infringement of intellectual property rights?

Highly ineffective (framework for litigation and penalties does not exist) ☐	Fairly ineffective (framework exists but is generally not implemented or enforced) ☐	Fairly effective (framework is generally implemented and enforced but the process allows for delays and additional costs in some cases) ☐	Very effective (including compensation, injunctions and penalties, without involving delays and additional costs to innovators) ☐

Question 25
To what extent is the biopharmaceutical industry able to provide information to patients on existing treatments in your country?

Not at all (information may only be given to physicians and/or in scientific publications) ☐	To a limited extent (very general information may be given about available treatments for a limited number of medical conditions, but industry is not allowed to refer to specific products) ☐	To some extent (information about the existence of available products to treat different medical conditions may be given, but without reference to names of product) ☐	To a great extent (information may be given on specific products, with reference to brand name, as long as such data is accurate and balanced, e.g. refers to limitations, risks etc.) ☐

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